IN RE: Bard IVC Filter Products Liability Litigation
USDC, District of Arizona, Case No. 2:15-MD-02641-DGC

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION FOR PROTECTIVE ORDER REGARDING REPORT OF DR. JOHN LEHMANN

LIST OF EXHIBITS

1. Phillips Trial. Ex. 946 (March 10, 2004, Health Hazard Evaluation) FILED UNDER SEAL
2. Phillips Trial. Ex. 682 (Email from Lehmann to Passero, April 15, 2004)
3. Phillips Tr. Ex. 714 (Email from Uelmen to Kellee attaching RAP, December 12, 2004)
4. Recovery Filter Chronology of Events FILED UNDER SEAL
5. Excerpts of Deposition of David Ciavarella, MD (November 12, 2013) FILED UNDER SEAL
6. Regulatory Affairs Manual, Rev. No. 8 FILED UNDER SEAL
7. Health Hazard Evaluations (HHEs) and Health Risk Assessments, (HRAs)
8. Excerpts of Deposition of Chad Modra (March 28, 2013) FILED UNDER SEAL
9. Phillips Trial Ex. 748 (Email from Greer to Hudnall, March 16, 2006)
10. Phillips Trial Ex. 1128 (Email from Lehmann to Glass, March 19, 2004)
11. Phillips Trial Ex. 517 (May 1, 2004, fax)
12. Regulatory Affairs Manual, Rev. No. 9 FILED UNDER SEAL
13. January 4, 2005, Remedial Action Plan (with Report Attached) FILED UNDER SEAL
14. Excerpts of Transcript of October 29, 2015, MDL Hearing
15. Letter from Lerner to Stoller, November 20, 2015

16. Order dated 3/28/14, *Payne v. C.R. Bard, Inc.*, Case No. 6:11-cv-1582-Orl-37GJK

17. Order dated 3/15/15, *Payne v. C.R. Bard, Inc.*, Case No. 6:11-cv-1582-Orl-37GJK 24.

18. Phillips Trial Ex. 1133 (Email from Ganser to Lehmann, April 23, 2004). FILED UNDER SEAL

19. Phillips Trial Ex. 864 (July 9, 2004, Draft Updated Health Hazard Evaluation)

20. Excerpts of Deposition of Christopher Ganser (February 28, 2011) FILED UNDER SEAL

21. Excerpts of Deposition of Douglas Uelman (October 4, 2013) FILED UNDER SEAL

22. Phillips Trial Ex 760 (enclosing Bard filter comparison chart)

EXHIBIT 1

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 2

To Plaintiffs' Response to Bard's Motion for Protective Order

John Lehmann

From: John Lehmann [jlehmann@lehmannthomas.com]
Sent: Thursday, April 15, 2004 3:07 PM
To: 'Lee Lynch'; 'Glass, Holly'; 'Passero, Donna'; 'Hudnall, Janet'; 'Jones, Kellee'
Cc: 'Kimberly Ocampo'
Subject: RE: Crisis Plan and Supporting Documents for your review

Lee I have reviewed the various documents attached to your email.

My telephones are as follows:
O: 617 489 7080
H: 508 358 5365
C: 508 341 8942

Our overall simple message needs to be:

1. A properly placed filter can resist the force of a fair amount of blood clot, but that large clots and the forces of exertions such as bowel movements can overwhelm any filter's retentive capability, resulting in migration.

2. This is true for all IVC filters.

3. This leads into the two key facts in this case:
   a. that the RF is a well designed and tested IVC filter that was properly placed and intact, and
   b. that the blood clot was massive and additionally propelled by straining at stool.

==> Bottom line: good filter, severe case, bad outcome, deep regret.

This is the simple story we should repeat again and again.

Comparison with other filters is problematic in many ways, and we should avoid / downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard, that " Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device."

As to review of the specific documents you forwarded:

The statement on page 20 0f the main communications plan as follows:

- Extensive migration resistance testing conducted ~~competitors~~ showed that the Recovery Filter was just as ~~resistant~~ or more resistant to migration than all retrievable and non-retrievable competitors (MUST CONFIRM)."

is not entirely accurate and does need revision. Should be discussed with BPV R&D and QA folks who've done the com at largest recommended IVC diameters the migration resistance drops substantially. BTW, I would think that the content herein does need review by John DeFord, Chris Ganser et al; I am presuming that you are doing this separately or at a later stage of drafting.

On page 21, the author has noted:

1. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

[OR CAN WE SAY: While the Recovery Filter did migrate, we believe the underlying cause of death was the accumulation and migration of a very large pulmonary embolism. An enormous blood clot, measuring 10 cm in length and 3 cm in diameter, was deposited around the filter over a period of several days. The clot was of such a massive size that it enveloped the filter and traveled through the bloodstream to the man's lungs, causing death.]

From the point of view of patient privacy, it is confidential information regarding the pathological findings, cause of death etc., so I am not sure we are entitled to disclose such information, with the exception of prior legitimate disclosure by others (such as family members). I would guess (needs legal concurrence) that we can disclose the testing results that we have had performed in relation to the filter, such as the RF was entirely intact and functional. Whether we can mention blood clot or size of clot is a legal question relating to HIPAA issues etc.

For the Internal Q&A document, I would recommend changing #7 to the following text:

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic injury and in obese individuals after weight reduction ("bariatric") surgery.

For the Internal Q&A document, the answer to Question #10 'who designed the RF' as 'NMT' is really not helpful to Bard, and certainly not to NMT. Bard bought, approved and sells the RF, and owns the design and its merits and demerits. Dinging NMT won't help the PR case, and will certainly piss off NMT. I'd find another way to handle this issue, such as "Bard purchased the product design and manufacturing from a valued partner, and has thoroughly assessed and tested the product, and stands behind its design in every way." or some such similar supportive and positive statement.

For the Internal Q&A document, Question #13 on physician training, be very careful on this one. It's not what you think you're doing, or what you told the FDA, but what you are actually currently doing. Get the straight story from the Sales force and don't dress it up.

For internal Q&A, Question #14 on complications, recommend changing to:

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

For Internal Q&A #15, the answer (text about various possible causes of migration) is not at all responsive to the question (about rate of migration for RF). The answer to #16 is the answer. Why don't you get rid of the A to #15 and the Q for #16, and combine the remains.

For Internal Q&A #17 - 18 on migration resistance testing, I wouldn't raise this subject if at all possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that altho RF was certainly within the boundaries of devices tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors"

Internal QA& #19 ditto

Internal Q&A #20. I would change the text for #20 to:

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and

fracture or failure of the filter wires. All marketed filters in the U.S. have reported instances of filter migration.

[If asked about Recovery Vena Cava Filter cases in which migration occurred, also add the following to the response: Of the six reported cases of the Recovery Filter migrating, five were caused by blood clots and one was caused by improper filter insertion.]

Internal Q&A #22 as follows:

1. *What are the dangers associated with filter migration?*

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would have generally have passed directly to the lungs, causing substantial harm on its own.

INternal Q&A #24 - 27: I'd like to get a read on the HIPAA implications of discussing any clinical information regarding this patient. If we are able to discuss such things, then the text for these needs some significant revision. If not (which might be preferable) we have to say that we cannot discuss confidential patient information in response to all such questions as to causation, death certificates text, etc. Let's discuss once Donna has ruled on what disclosure is permissible in various circumstances.

External Q&A's:
#6 on what is a pulmonary embolus: see remarks above for Internal Q&A #7

#9 on training: see Internal Q&A #13 above

#10 on complications: see Internal QA& #14 above

#12 on causes of filter migration: see Internal Q&A #20 above

#13 on comparative migration resistance: see multiple caveats above

An area that is not covered is the MAUDE database. If we get a reporter pressing questions on the number of reports, then we will have to deal with this sticky area. That means we have to have sales estimates, and tabulations of MAUDE entries (as already prepared by BPV staff) and calculations of rates; as well as someone comfortable with quantitative presentation skills and credibility.

RE medical literature summaries: can't comment, I'm on the road w/o the references. Practically speaking, we need to make sure that our physician spokespersons have all these references and the summary in a well organized binder, so that they can refer to them rapidly.

Hope this helps.

Regards, John Lehmann

From: Lee Lynch [mailto:LLynch@HillandKnowlton.com]
Sent: Tuesday, April 13, 2004 6:07 PM
To: 'Glass, Holly'; 'Passero, Donna'; 'John Lehmann'; Hudnall, Janet; 'Jones, Kellee'
Cc: Kimberly Ocampo
Subject: Crisis Plan and Supporting Documents for your review

PRIVILEGED AND CONFIDENTIAL

Hi everyone -

Through conversations with Janet, Donna and Holly, we have secured enough information to create complete initial drafts of the Recovery Vena Cava Filter Crisis Plan and corresponding documents; each of these documents is attached for your review:

- Full Crisis Plan. Included in the Appendix section of the Crisis Plan are additional documents for your review, including:
  - General Key Messages
  - Miami incident-specific key messages
  - General Letter to the Editor
  - Miami incident-specific Letter to the Editor
- Internal Q&A
- External Q&A
- Medical Study Summaries

We'd like to ask you to review all of the documents this week, then join us for a call to go through your revisions sometime early next week. Can you let us know your availability on Monday and Tuesday of next week?

Questions for consideration and feedback are highlighted in yellow within the documents.

In addition, we have a number of questions we are hoping to have the following individuals answer directly to us by e-mail this week, including:

For Kellee Jones:

- Contact information for Chris Ganser and Doug Uelmen

For Janet Hudnall:

- Mobile number
- Is it OK to add Carol Stone under the key contact for the Field Sales Reps in the Audience Response Team section of the Crisis Plan?
- Are there any physicians NOT paid by Bard who can serve as spokespeople? If not, could you follow up with Drs. Venbrux and Kaufman regarding their interest and availability? To that end, please confirm that these physicians indeed have been paid by Bard for training and speaking.
- Is it OK to add the Society of Vascular Surgeons as an ally organization?
- Can you provide us with the following studies: Kaufman and Venbrux for FDA approval and the Special Access Canadian study?
- Are there any other human studies to add to the "Medical Study Summaries"?

Many thanks for your help! Lee Lynch and Kimberly Ocampo, H&K

EXHIBIT 3

To Plaintiffs' Response to Bard's Motion for Protective Order

From: Uelmen, Doug [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=DUELMEN]
Date: 12/12/2004 10:36:22 PM
To: Jones, Kellee [Kellee.Jones@crbard.com]
Attachments: SPA-04-12-01.doc

Remedial Action Plan (Revised)
Bard Peripheral Vascular Division
SPA-04-12-01
December 9, 2004

I. Product Description and Intended Use

A. The Recovery Filter consists of twelve shape-memory nitinol wires emanating from the central nitinol sleeve. These twelve wires form two levels of filtration. The legs provide a lower level of filtration and fixation to the caval wall. The arms provide the upper level of filtration and help center the filter in the vessel. The Recovery Filter is intended to be used in vena cava circular diameters up to 28 mm.

B. The Recovery Filter Delivery System consists of a 7 French I.D introducer sheath and dilator, the Recovery Filter, a delivery storage tube with saline infusion port, and a pusher system. The Recovery Filter is packaged pre-loaded within the delivery storage tube.

C. The Recovery Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter is indicated as a permanent filter or implanted temporarily to treat the temporary risk of pulmonary embolism. The Recovery Filter has the following indications for placement:

1. Pulmonary thromboembolism when anticoagulants are contraindicated.
2. Failure of anticoagulant therapy in thromboembolic disease.
3. Emergency treatment following massive pulmonary embolism where the anticipated benefits of conventional therapy are reduced
4. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

II. Manufacturer / Distributor

A. The product is manufactured by the Bard Glens Falls Operation, Queensbury, NY and distributed by the Bard Peripheral Vascular Division through the Bard Distribution Center, Covington, GA

III. Identification of the Problem

A. A consultant was commissioned by Corporate Senior Management to provide an independent study of the risk / benefit of the RNF in bariatric

patients. While preparing data for this study, several unfavorable comparisons were discovered. These data comparisons are being addressed in this remedial action plan.

1 This comparison included:

a) The Simon Nitinol Filter (C.R. Bard)
b) The VenaTech Filter (B Braun)
c) The Titanium & SS Greenfield Filters (Boston Scientific)
d) The Bird's Nest Filter (Cook)
e) The Günther Tulip Filter (Cook)
f) The TrapEase Filter (Cordis)
g) The OptEase Filter (Cordis)

2. Comparative data was obtained from the following sources:

a) The FDA MAUDE database (2000 to present). MDR reports for each of the filters were used as a measure of field performance.
b) The IMS database was used to provide sales data.
c) BPV bench test data.

3. Rates were developed using the MAUDE & IMS data. These rates were normalized by the consultant to show adverse events per 100,000 units used.

4. Normalized data was used to compare the RNF to the above mentioned filters in the following catagories:

a) Fatalities associated with migration.
b) Non-fatal migrations.
c) Vena cava perforations associated with fractures
d) All deaths.

5. For each comparison a statement of releative risk was developed. The relative risk provides a multiple of the risk associated with RNF when compared to:

a) All ICV filters individually.
b) IVC filters with a retrievable indication.
c) All ICV filters as a group.

6. The comparison provided by the consultants indicates a signicant differnce in the catagories studied between the RNF and other filters (see attachment A).

IV. Medical Evaluation

A. See Heath Hazard Evaluation report attached.

V. Number of units and lots involved:

A. As of December 9, 2004, there have been approximately 20,597 Recovery Filter units distributed since the product was released in April 2003.

VI. Distribution of Units

A. Recovery Filters are distributed in the United States, United Kingdom, Canada, Australia, Italy and Benelux.

VII. Action Plan:

A. A Division Investigation Team (DIT) was assigned to review the data associated with the identification of the problem (above). This team included the BPV VP of QA, the BPV VP of RA/CA, the BPV VP of R&D, the Director of R&D for Interventional Products, and the IVC Filter Marketing Manager. In addition, two members of the RA staff were assigned to provide independent confirmation of the MAUDE database review.

1. The DIT completed a review of all IVC Filter MDRs found in the MAUDE from Q1 200 through Q3 2004. Clarifications and corrections were completed and discussed with the Corporate Consultant. Upon completion of this activity, both the Corporate Consultant and the DIT concur that the database being used for comparison is in agreement with the MAUDE database. The DIT continues to hold view that the value of the MAUDE database does not yield reliable quantitative estimates because the number of MDRs are likely to be underestimated by unpredictable yet significant reporting issues.
2. The Division Investigation Team believes that although the IMS database can be a useful marketing tool, it has the following limitations when attempting to provide detailed sales data needed to yield precise rate comparisons. Due to these limitations, only mean data has been provided to the Corporate Consultant for this comparison (95% confidence interval: mean $\pm$ 27.3%).

a) The IMS database is a retrospective sampling of sales from approximately 5% of U.S. Hospitals (350 of 6,000).
b) The current published IMS report is from Q2 2004, which contains Q1 2004 actual sales.
c) Because it is the companies' responsibility to inform IMS of new product introduction, there is a delay associated with updating the IMS database, resulting in inaccurate information.
d) Procedure-based databases (SMG) tend to be more closely aligned with the lower end of the IMS confidence interval.

3. Sales/Procedure Data Source Comparison
   a) IMS – Market data estimated from the sales data of 350 out of 6000 U.S. hospitals. The Hospital Supply Index precision tables can be used to estimate the 95% confidence interval for the mean data that is presented in the quarterly IMS reports.
   b) Millenium – Market projection
   c) Medtech Insights – Market projections
   d) Solucient – Procedure data
   e) Verispan (SMG) – Procedure data collected from 100% Medicare patients and 100% of the private-pay patients from 21 of the states, used to project the total of private-pay patients.

Source	*2002*	*2003*	*2004*
IMS (Mean)	113,697	124,020	not available
IMS (Lower 95% CI)	82,317	89,790	not available
IMS (Upper 95% CI)	145,077	158,250	not available
Millenium	94,000	97,000	100,800
Medtech Insights	100,000	111,000	126,000
Solucient	75,813	85,287	not available
Verispan	72,563	80,439	not available

4. The following comparative table provides an overview of the adverse events associated with each IVC filter presently on the market:

Brand	Migration	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Insertion
SNF	3	9	0	0	3	25
RNF	82	36	0	20	31	36
VenaTech	52	0	0	2	2	31
Greenfield	22	5	1	2	4	97
Bird's Nest	31	124	0	15	77	124
Tulip	36	20	3	3	0	56

TrapEase	12	10	36	3	6	15
OptEase	12	0	12	24	12	35

*rates per 100,000 patients

a) Predominant failure mode associated with RNF is migration (3X industry average).
b) Predominant failure mode associated with TrapEase is caval thrombosis (16X).
c) Predominant failure modes for Bird's Nest include perforation (11X), fractures (9X), and insertion difficulties (3X).

B. *The DIT concludes there is no perfect filter.*

1. The DIT has reviewed the BPV database and found the following:
   a) 3 of 6 migration related deaths were associated with the bariatric population.
   b) 1 of 6 migration deaths were associated with trauma patients.
   c) 2 of 6 migration deaths were associated with DVT patients contraindicated for anticoagulation.
   d) 7 of 16 total migrations were associated with bariatric patients.

2. Product Utilization. (Insert Joe's data)
   a) 16% of total utilization is in bariatric surgery.
   b) 50% of the migration related deaths have been reported for the bariatric population.
   c) 44% of the overall migrations have been reported for the bariatric population.
   d) The bariatric patient population is highest risk patient population presently receiving the RNF.

3. Bariatric Patient Population Removal Effect on rates/regression analysis:
   a) Rates:

RNF Migration/Death Rate

Condition	Sales (units)	Total Migrations	Total Mig./Deaths
All Recovery	19,537	0.082% (16)	0.031% (6)
Without Bariatric	16,411	0.055% (9)	0.018% (3)

Total Fatality Rate Comparison

Brand	LCI	All Deaths	UCI
SNF	0.000%	0.000%	0.000%
Recovery	0.018%	0.018%	0.018%
VenaTech	0.009%	0.007%	0.006%
Greenfield	0.009%	0.007%	0.005%
Bird's Nest	0.020%	0.015%	0.012%
Tulip	0.014%	0.011%	0.009%
TrapEase	0.016%	0.012%	0.010%
OptEase	0.030%	0.024%	0.019%
Recovery to all filters	1.30x	1.65x	2.10x

*LCI is most consistent with procedural databases.

b) Regression analysis with/without bariatric patients

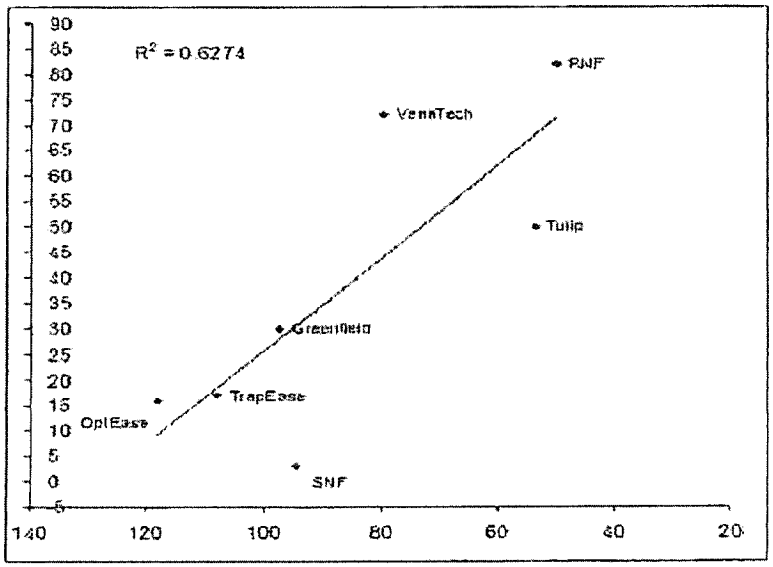

TABLE XX: With RNF Bariatric Population
Note: All Migrations normalized to 100,000 vs migration resistance bench data (average 25-32mm)

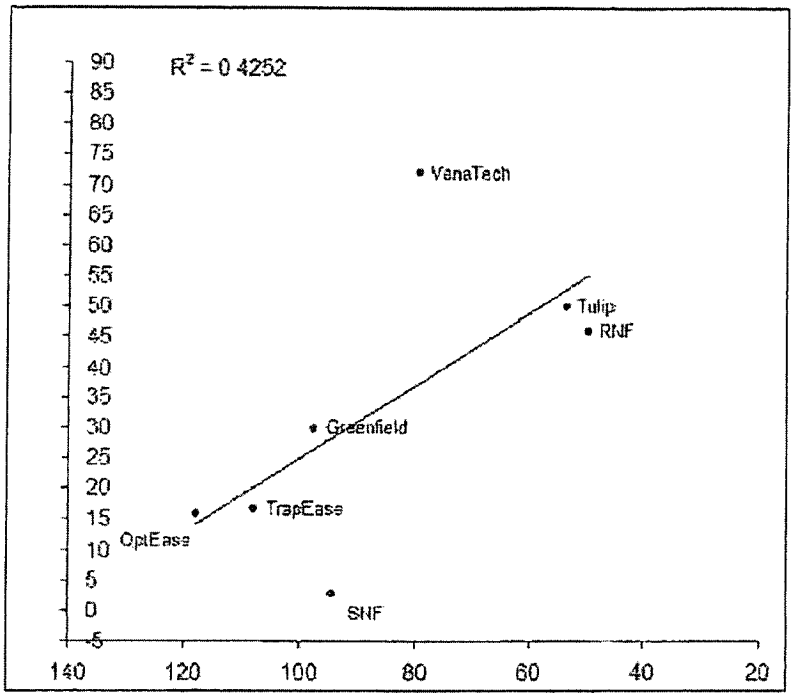

Table XX: RNF without bariatric population
Note: All Migrations normalized to 100,000 vs migration resistance bench data (average 25-32mm).

C. The following provides a list of opportunities to mitigate the predominate failure mode associated with RNF (migration).

1. No Action until G1a becomes available.
   a) Not Recommended: DIT believes that BPV data is compelling as to sub-population of bariatric patients.

2. No immediate action while additional data is gathered (survey, Q4 Maude).
   a) Not Recommended: Internal data is adequate to make recommendation regarding sub-population.
3. Inform and Warn
   a) Safety Alert- Warning
      (1) (1) Recommended: Appropriate to reduce death and major complication rates. Physician/patients may still choose Recovery Filter based on updated information.
   b) Safety Alert – Contraindication
      (2) (1) Not recommended: For bariatric patients, the RNF provides a necessary benefit to prevent lethal PE. (10x less likely to die) Sapala, et al. *"Fatal Pulmonary Embolism after Bariatric Operations for*

Morbid Obesity: a 24-year retrospective analysis" *Obesity Surgery, 13, 819-825.*

4. Market Withdrawal.

b) a) Not Recommended: Filter provided benefit to 99.8% patients treated. Reducing number of bariatric patients treated will reasonably reduce number of migration-related complications.

EXHIBIT 4

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 5

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 6

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 7

To Plaintiffs' Response to Bard's Motion for Protective Order

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs)

FDA learns of problems with medical devices in different ways. Most often, a firm will notify its customers and FDA that it is issuing a recall. At other times, FDA's analysis of medical device reports will indicate a greater than expected failure rate. In either of these cases, FDA must review the risks to determine the actions needed to resolve them.

Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs) are the processes that FDA follows to determine the risks of certain device problems and the actions firms should take to resolve them. HHEs and HRAs are designed to reflect the language in the recall regulations and are used specifically for recalls and related safety work. HHEs and HRAs follow the same process and use the same documentation, but they serve slightly different purposes:

- **HHE** is a tool for classifying a voluntary recall by a firm. The evaluation g uides FDA in determining the risk to the public from the defective product and appropriate actions for the firm and the FDA to take to protect public health.
- **HRA** is a tool for predicting possible harm that can come from a defective or malfunctioning device. The assessment helps the FDA and the firm determine if any actions are necessary such as recalling the devices or notifying the public about the risk.

Collecting and Reviewing Device Information

An FDA physician may conduct an HHE or HRA alone, or FDA may convene a committee of physicians, engineers and other scientists to reach consensus on the level of risk posed by a specific device problem.

In an HHE or HRA evaluation, the physician or committee collects and reviews a wealth of information about the device to gain a better understanding of the problem. They start with basic information, such as the manufacturer, the number of devices in use, the intended use of the product, and the number of devices subject to recall, if one occurs.

They also consider the specific problem with the device, including information known about the cause, to determine how likely the device is to fail and how serious this might be to users. The risk may be related to problems with the design or manufacture of the device, or it may be due to errors made by users.

The physician or committee then reviews a summary of the investigation and analyzes adverse events, complaints, and problems that may be related to the device defect. They also consider the likelihood of disease, injuries, and death as a result of exposure to the defective device, as well as factors that may reduce the risk of harm. This involves forecasting the frequency and severity of health consequences among two groups of people – those at greatest risk (infants, the elderly, pregnant women, the critically ill, and people with compromised immune systems) and everyone using the device.

All the information taken together allows the physician or committee to characterize the total health

risk of the device and support the agency decisions and recommendations that follow.

Additional Information

- **Health Hazard Evaluation Form--MSWord (DOC - 169KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/UCM126211.doc)**

More in CDRH Transparency (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/default.htm)

Overview of CDRH Transparency (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199624.htm)

Total Product Life Cycle (TPLC) (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199906.htm)

Premarket Submissions (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199907.htm)

Postmarket Performance and Safety (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199909.htm)

Compliance & Enforcement (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199911.htm)

Science & Research (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199912.htm)

Educational Resources (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199913.htm)

CDRH Performance Data (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199915.htm)

CDRH Transparency Website Feedback Summary (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm214646.htm)

EXHIBIT 8

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 9

To Plaintiffs' Response to Bard's Motion for Protective Order

From: Greer, Jason [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=JGREER]
Date: 3/16/2006 2:32:37 AM
To: Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: say crazy
Attachments: image001.jpg, image002.jpg

Hey, when you go about choosing speakers for filter breakouts, please consider Nicole. She is doing some really cool stuff...some of it I can talk about...some I can't. However, her knowledge of low molecular weight heparin and heparin is allowing her to take over the market. Another guy that knows his Shiite on filters and is worth considering is Fecher. I swear, the guy is a walking encyclopedia of filters. He is a young John Timko. He wakes, eats, sleeps filters.

I'm going to call you tomorrow.....crazy.

We were on vacation in San Antonio. It was so awesome. The kids went to Sea World and Six Flags. The Westin there has an awesome set of pool just for the kids. It was 90 degrees but pleasant. I even took a nap. I've take about 10 of those in my adult life.

BTW, you know what I was thinking about today? I was thinking how far we've come in a year as far as filter problems. I know we are having a few problems but do you freaking remember what it was like a year ago? Do you remember what it was like 2 years ago? I don't know if it can ever get any worse. You weathered the storm as well as anyone, anyone could have. If you do decide to interview for new positions, you better document what you did because I don't think there are many better business case studies for a terrible situation that was held together with scotch tape, smoke, mirrors, crying, etc. You should be pretty proud of yourself.

Also, Ben is going to work with Dave Steam at Cardiomim(sp?). Don't tell him about the affair. It's over.

Jason Greer

District Sales Manager

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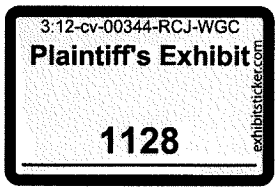
EXHIBIT 10

To Plaintiffs' Response to Bard's Motion for Protective Order



From: John Lehmann [jlehmann@lehmannthomas.com]
Date: 3/19/2004 2:20:15 AM
To: 'Glass, Holly' [Holly.Glass@crbard.com]
CC: 'Uelmen, Doug' [Doug.Uelmen@crbard.com], 'Passero, Donna' [Donna.Passero@crbard.com], 'Lee Lynch' [LLynch@HillandKnowlton.com], 'Ganser, Christopher' [Christopher.Ganser@crbard.com]
Subject: RE: Recovery Crisis Communications Plan
Attachments: Notebook.jpg

Holly, glad to help.
I will be on travel status starting tomorrow night til next Wednesday, and then again from next Thursday thru April 13th, so I can't be of much help during that period.
Regards, John

From: Glass, Holly [mailto:Holly.Glass@crbard.com]
Sent: Friday, March 12, 2004 10:30 AM
To: jlehmann@lehmannthomas.com
Cc: Uelmen, Doug; Passero, Donna; Lee Lynch
Subject: Recovery Crisis Communications Plan

Dr. Lehmann:

As you may be aware, I am working with Hill and Knowlton to prepare a comprehensive crisis communication plan in the event the Recovery issue is "exposed" in the media. We have formed a team of the H & K reps, myself, Donna Passero, and Janet Hudnall to work on the components of the plan.

From time to time, it will be imperative to have the medical expertise represented on the team and wanted to ask if you are willing to help us on an as-needed basis? Most likely it will involve joining all or part of pre-arranged conf. calls and/or an in-person meeting in Washington over the next month or two.

Thanks -
Holly Glass

Holly P. Glass
Vice President, Government and Public Relations
C. R. Bard, Inc.
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703-754-2848
703-754-7889 fax
571-243-1952 cell

Lehmann Thomas, LLC

Memo

To: Doug Uelmen, BPV

From: John Lehmann, MD

Cc: Brian Barry, Corporate
Paul Kowalczyk, Corporate
Chris Ganser, Corporate

Date: March 10, 2004

Re: Recovery Filter Migration HHE

Doug, here's the Health Hazard Evaluation.

Regards,

John W Lehmann MD

Summary of Health Hazard Evaluation: A case of vena cava filter migration associated with patient death was reported after the successful implantation of a Bard Recovery® Nitinol Vena Cava Filter. Evaluation demonstrated an intact filter and a massive thromboembolic event involving both clot and filter lodging in the right heart. Several other filter migrations were also reviewed.

Conclusion: Vena cava filter migrations are a recognized and accepted complication of this type of therapy. Such complications may be serious and can occasionally be fatal. The evidence to date does not suggest that these types of events are occurring with excess frequency with the Bard Recovery® Nitinol Vena Cava Filter.

Description of the problem: A complaint in February, 2004 regarding a Bard Recovery® Nitinol Vena Cava Filter (Recovery VC Filter) migration associated with a patient death led to a review of the potential health hazard associated with such occurrences.

Actual occurrence of injuries: The index case involved a 34 year old morbidly obese male, who just prior to laparoscopic gastric bypass had a normal and uneventful placement of the Recovery VC Filter in a straight, 23 mm vena cava just below the renal vessels. This was confirmed by the author's review of the procedural radiographs, which demonstrate a straight, nonanomalous vena cava measuring approximately 22 – 23 mm in diameter; the implanted Recovery VC Filter appeared to be roughly centered with all its arms and legs extended without crossing.

The patient had multiple risk factors for pulmonary embolic disease: morbid obesity, venous stasis disease, sleep apnea syndrome, probably mild / moderate congestive heart failure and the perioperative state induced by the proposed surgery. Laparoscopic surgery was uneventful; the postoperative course apparently involved intubation and central line placement for at least three days after surgery. confirmed by chest X-rays which also suggested either CHF or volume overload. On the 5th postoperative day, the patient collapsed while on the toilet and could not be resuscitated.

Key features noted in the preliminary autopsy report included:

- "large thromboemboli and inferior vena cava filter in the right atrium"
- no mention of status of pulmonary vasculature
- no other evident cause for acute death except "dark red areas in the papillary muscle and left ventricular myocardium" possibly consistent with acute myocardial infarction
- intact gastric surgery
- evidence of CHF ± volume overload ("bilateral pulmonary congestion, lower lobes", "cardiomegaly (710 grams)", "congestive splenomegaly (510 grams)" and "congestive hepatomegaly with fatty change (3200 grams)"

The thromboembolus and contained Recovery VC Filter were photographed at autopsy, and reveal a massive clot, measured from the photograph as approximately 4½" in total

length along an irregular longitudinal access and approximately 1¼" in diameter at its widest point. The Recovery VC Filter was partially contained at what appears to be the leading edge of the aggregated thrombus material.

The thromboembolus was forwarded to Dr. Luke Brennecke for pathologic investigation, which as of the writing of this HHE is incomplete pending final histopathology. Based on currently available data, Dr. Brennecke found the specimen, now having been in 10% formalin since the autopsy, to measure approximately 10 cm long and 3 cm in diameter at its thickest point. The clot formed ante mortem. Radiographs of the Recovery VC Filter showed that the device appeared normal in configuration and with its arms, legs and hooks intact. Some of the hooks were embedded in the thrombus.

Assessing all available data, the current assessment of this event was massive thromboembolic impaction of the right atrium leading to acute circulatory collapse and death in a patient with a normally placed, intact Recovery VC Filter. The appearance of the thromboembolus and embedded filter is that of an aggregated, massive clot burden that developed sufficient cephalad force to move a normally implanted and intact Recovery VC Filter downstream to the heart.

Other Recovery VC Filter migration complaints were then reviewed:

- Redacted: asymptomatic, discovered on Day 16 to have migrated to renal veins, removed without incident, filter found to contain "large amount of thrombus"
- Redacted: asymptomatic, discovered on Day 1 to have migrated to renal veins, removed without incident, filter free of thrombus material.
- Redacted: patient c/o chest pains (? relation), on Day 13 filter found to have migrated 4cm cephalad (above the renal veins), large clot noted, device not removed as of date of report
- Redacted: patient c/o shortness of breath and light headedness, on Day 13 filter found at IVC / RA junction with large amount of clot in the filter and elsewhere, patient underwent CP bypass and open surgery for removal of clot from pulmonary arteries, RA, IVC, and removal of filter without intraoperative or postoperative difficulties.
- Redacted: inexperienced physician misdeployed filter, then used nonstandard correction procedure which led to embolization of the filter to the right heart. This ultimately required open chest retrieval via pulmonary artery access, with ultimate outcome unknown as of this writing.

Human exposure to the problem: Embolism of vena cava filters is a generic and well recognized risk of this technology. Events have been reported in the medical literature since the early 1980s as well as in the MAUDE database; these reports include migrations to the heart and include fatal outcomes.

Male and female patients at risk of pulmonary embolism who are either unable to take anticoagulants, are anticoagulant failures, or who are at unusually high risk are generally

indicated for the use of vena cava filters in general and the Recovery VC Filter in specific.

General consequences: Migration of vena cava filters can have minimal consequences in some patients. In others it result in caval or renal vein obstruction, damage to the vena cava, and if the device and associated thrombus lodges centrally, release of thrombus with pulmonary embolization, as well as direct impairment of cardiac function including valvular dysfunction, reduced cardiac output, circulatory collapse and death.

Population exposed to risk: Generally adult patients with a high risk for pulmonary embolic disease.

Mitigating/predisposing factors in population at risk: Mitigating factors include the close medical attention such patients generally receive. Predisposing factors in this population include coagulation abnormalities, obesity, sleep apnea syndrome, perioperative condition, congestive heart failure, cardiac arrhythmia and anticoagulant intolerance / failure.

Nature and seriousness of the risk: The nature of the risk ranges from minimal (asymptomatic migration without sequelae) to catastrophic (acute circulatory impairment from pulmonary or cardiac embolization with clot, filter or both). The latter risk is serious and potentially fatal.

Likelihood of occurrence of problem: There have been 3 migrations of the Recovery VC Filter in which the device ended up in or near the heart, with one fatality, in an estimated 6,402 sales through March 2, 2004, for a rate of 0.05%. One instance was a deployment error, the other two occurred after apparently normal deployments on Day 6 and Day 13. These types of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature.

Comparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates for two major reasons: the numerators are likely to be underestimated by unpredictable yet significant underreporting, and the denominators (sales data) are closely held numbers not released by manufacturers. However, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported.

Likelihood of harm if problem occurs: The likelihood of harm if the Recovery VC Filter migrates to or near the heart is significant, but unquantifiable.

Is product essential to health?: Yes, vena cava filters are essential to health for the indicated patients, who may have no other alternative to prevent pulmonary embolism.

Is an alternative available?: Yes, other manufacturers currently sell approved vena cava filters, and there are also other medical and surgical options for some of these patients.

Must the problem be corrected surgically?: Migration of vena cava filters to the heart is rarely managed conservatively, and treatment almost always requires either a percutaneous or open surgical correction.

Is the problem expected and within an acceptable statistical range?: Migration of vena cava filters, both within the vena cava and up to and into the heart are recognized complications of these devices. Acceptable statistical ranges cannot be reliably computed from available data. Estimates based on MAUDE and sales data suggest that there is no significant difference in the rates of these complications between devices, including the Recovery device.

Can the problem be field corrected? The device appears to have been functioning normally, but was overwhelmed by an aggregated, massive thromboembolus combined with physiologic stress, leading to migration of the filter. There is no device problem to be field corrected in this instance, just a recognized complication of vena cava filters.

Is it obvious to the user?: Migration of vena cava filters can be asymptomatic, but when they migrate to the heart this is clinically evident.

Can the product continue to be used with proper warnings?: Yes, the product can continued to be used with current warnings, which indicate the possibility of filter migration.

Is the device used only by specially trained health care professionals?: Yes, the device is only used by interventional radiologists and occasionally by other equally skilled interventionalists.

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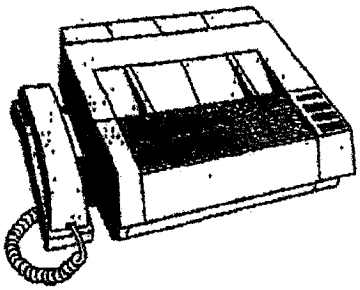
EXHIBIT 11

To Plaintiffs' Response to Bard's Motion for Protective Order

C. R. BARD, INC.
730 CENTRAL AVENUE
MURRAY HILL, NJ 07974

Fax# 908-277-8087
Tel # 908-277-8341
E-Mail: paula.pizzi@crbard.com



FAX

TO: Mary Edwards

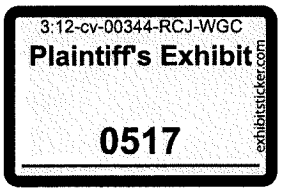
FROM: Paula Pizzi for Paul Kowalczyk

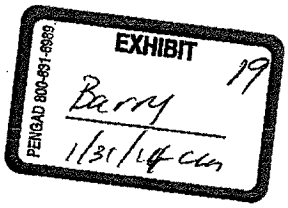
DATE: May 11, 2004

NUMBER OF PAGES INCLUDING COVER SHEET: 56

If transmission is not complete, please notify sender at (908) 277-8341.

COMMENTS:





Church, Nikki

From: Barry, Brian
Sent: Monday, May 10, 2004 4:05 PM
To: 'Kimberly Ocampo'; Church, Nikki
Cc: Ganser, Christopher; Kowalczyk, Paul
Subject: RE: Latest Bard Filter Plan and Q&As

Kimberly:

Hi, per my discussion with Chris Ganser, this piece will need to go through the standard Bard approval process for external pieces.

To that end, per copy of this email I am forwarding this piece to Nikki Church of our law Department, who coordinates such reviews. Nikki, please log and route per standard procedure.

Thanks

Brian

Brian R. Barry
V.P. Corporate Regulatory & Clinical Affairs
C.R. Bard Inc.
730 Central Avenue
Murray Hill NJ 07974

908-277-8062
908-277-8087 (fax)
908-472-5177 (cell)

-----Original Message-----
From: Kimberly Ocampo [mailto:kocampo@HillandKnowlton.com]
Sent: Monday, May 10, 2004 11:24 AM
To: Barry, Brian
Subject: FW: Latest Bard Filter Plan and Q&As

Hello Brian. Please see below. I'm not sure if I was given the correct spelling of your last name. Thank you.
-----Original Message-----
From: Kimberly Ocampo
Sent: Monday, May 10, 2004 11:19 AM
To: 'brian.berry@crbard.com'
Cc: Lee Lynch; 'Glass, Holly'; 'jlehmann@lehmannthomas.com'; Passero, Donna; 'Hudnall, Janet'; 'john.mcdermott@crbard.com'; 'christopher.ganser@crbard.com'; 'doug.uelmen@crbard.com'
Subject: Latest Bard Filter Plan and Q&As

Dear Brian:

On behalf of the Bard Team currently involved with development of the crisis plan and associated materials in support of the Recovery Filter, please review the attached draft communications plan, internal Q&A and external Q&A. These drafts incorporate the comments from the following: Dr. John Lehmann, Donna Passero, Janet Hudnall, John McDermott, Chris Ganser, Doug Uelmen and Holly Glass.

Could you please provide your edits and comments to Hill & Knowlton (Lee Lynch at llynch@hillandknowlton.com or 571.214.8799 or myself) by close of business, Wednesday, May 12? If you have any questions about these documents, please contact Holly Glass, Lee

or myself.

Once we incorporate your changes, we will distribute the latest drafts to the entire team and schedule a call to discuss further edits next week.

Thank you.

Regards,

Kimberly Ocampo

Kimberly Ocampo
Senior Account Supervisor
Hill & Knowlton Washington, D.C.
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HILL & KNOWLTON

"Best in International PR - Thomas L. Harris/Impulse Research

[redacted]

HILL & KNOWLTON

MEMO

To: **Holly Glass, Chris Ganser, Janet Hudnall, Donna Passero and Brian Berry**

From: **Lee Lynch and Kimberly Ocampo**

Date: **May 10, 2004**

Subject: **Recovery Filter Crisis Communications Plan**

This document provides a step-by-step guide for implementing an immediate communications strategy to ensure C.R. Bard is prepared for any news coverage that may result from pending investigations surrounding the Recovery Vena Cava Filter.

The information presented in this plan is privileged and confidential and is for internal use only.

HILL & KNOWLTON 600 New Hampshire Avenue, NW Suite 601 Washington, DC 20037 T 202 333-7400 F 202 333-1638

RECOVERY® FILTER CRISIS COMMUNICATIONS PLAN **5/10/04**

OVERVIEW

As with previous crisis plans Hill & Knowlton has prepared for C. R. Bard, this guide will help Bard's Corporate Communications Team prepare for and properly manage controversial or negative stories surrounding the Recovery® Vena Cava Filter.

The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, and longstanding reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

Currently, Bard is investigating the reported migration of the Recovery Vena Cava Filter in two separate incidences.

The first reported incident under investigation took place at Baptist Hospital of Miami, FL following bariatric surgery. The coroner's report stated that filter migration is the cause of death. Bard is conducting its own investigations to research the validity of this claim and hired Dr. Luke Brennecke of Pathology Associates in Frederick, MD to conduct a subsequent pathological evaluation of the thrombus surrounding the vena cava filter removed during the autopsy.

The summary provided in the CMP12933 PATH Report signed by Dr. Brennecke follows:

The clot formation was an ante mortem event; it had most likely been deposited around the device over a period of a couple of days. The location of the device during clot deposition could not be determined. The bacterial colonizing the clot most likely represents post mortem growth of normal saprophytic bacteria. Because extensive (destructive) sampling of the clot was prohibited (telephonic instructions), no tissue was sampled from around the hooks that were still embedded within the clot. Should they be sampled, it is possible that segments of the mural architecture (IVC or elsewhere) might be present.

It is important to note that, according to hospital records, the patient was a morbidly obese male weighing between 450 – 500 lbs. The filter was placed in a normal sized vena cava and there were no immediate complications. According to a Pathology Associates report, the filter was found to be intact, and the large thrombus surrounding the filter was approximately 10 cm long X 3 cm in diameter. To date, no formal lawsuit from the family of the deceased has been filed.

The second incident took place in Grand Rapids, MI. From the information available to date, we know that the Recovery Filter was placed in a female patient for deep vein thrombosis. The filter had been placed approximately 13 days prior to death, March 31, 2004. The patient was then released from the hospital on April 6, 2004 and expired on April 13, 2004. The medical examiner's report states that the cause of death is cardiac rupture as a result of a puncture to the right ventricle by an inferior vena cava filter.

The size of the clot at the time of the autopsy was approximately 3 cm in diameter by 50 cm in length. There were no design or manufacturing defects found to be associated with the filter. The BPV Product Assessment Team has concluded that the Recovery Filter captured a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilation greater than 28 mm resulting in migration. Final autopsy report will be available during the week of May 4.

The attached pages provide recommendations and critical information relating to the following components of your crisis communications program:

- I. Re-distributing Bard's Communications Policy
- II. Media Monitoring
- III. Message Approval
- IV. Establishing A Core Response Team
- V. Audience Outreach Team
- VI. Top Media Interview Dos and Don'ts
- VII. External Allies/Experts
- VIII. Key Studies
- IX. News Breakdown
- X. Newsmaker's Bill of Rights
- XI. Proactive Media Outreach
- XII. Step-by Step Management of Most Likely Scenarios:
- XIII. H&K Team Contact Information
- Addendum:
  - A. Key Messages – Recovery Vena Cava Filter: General Messages
  - B. Key Messages for Specific Incidents:
    - Specific to Miami Incident
    - Specific to Grand Rapids, MI Incident
    - Specific to Both Incidents
  - C. Draft General Letter-To-The-Editor
  - D. Draft Miami Letter-To-The-Editor
  - E. Draft Miami Letter-To-The-Editor
  - F. Media Lists
  - G. Recent Sample Article: Bariatric Surgery in General

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I. Re-distributing Bard's Communications Policy

To prevent any Bard employee from speaking with members of the media, it would be wise to redistribute Bard's communications policy company-wide twice each year beginning with 2Q 2004. If Bard is notified that a lawsuit has been filed, dissemination of the communications policy *again* specifically to the Bard Peripheral Vascular Division as well as C.R. Bard Corporate employees, should be considered.

Anyone who may be most likely to receive phone calls from members of the media (e.g., administrative staff for corporate executives and field sales representatives who sell vena cava filters) must have copies of the communications policy and should be required to sign a confirmation form that they have read and understand these guidelines.

All Bard employees must know to direct any media inquiries directly to Holly Glass. With the communications guidelines redistributed several times each year, employees will have this information top-of-mind.

II. Media Monitoring

H&K has begun monitoring regularly for any print, broadcast and online news coverage related to the company or the Recovery Vena Cava Filter. To do this effectively, H&K is using the Factiva database, Google News and Video Monitoring Services (VMS). Particular emphasis is placed on news generated from the following markets: greater New York City (Bard Corporate HQ); Tempe, Arizona (Bard Peripheral Vascular HQ); Miami, Florida (location of case under investigation) and Grand Rapids, Michigan (location of case under investigation).

We are searching for the following terms.

- C.R. Bard
- Bard Peripheral Vascular
- Recovery Vena Cava Filter
- Vena cava filter
- Pulmonary embolism
- Baptist Hospital (Miami, FL)
- Miami Cardiac & Vascular Institute (MCVI)[NA1]
- [NAME OF LAW FIRM FILING SUIT IF SUIT IS FILED]
- Any filter mentions in Grand Rapids, MI

III. Message Approval

Key messages (see appendix, still to be reviewed and finalized) serve as the foundation for responding during any media interviews that may arise as a result of the pending investigations. It is critical that this messaging be updated as new details arise.

The approved messaging will be incorporated into external materials that will be distributed to Bard's sales force, customers, physicians, employees, suppliers and others, as needed. Bard is then prepared to handle any media inquiries. Furthermore, H&K's on-camera Q&A Training will help prepare spokespeople for any local or trade press inquiries that are posed; additional "on-the-spot" training and messaging discussions should be considered prior to responding to national top-tier press inquiries.

IV. Establishing A Recovery Core Vena Cava Filter Response Team

The following Bard and H&K employees should comprise the Core Response Team (CRT) for the Recovery Vena Cava Filter product. These individuals will receive notification when a press inquiry is received or when a negative article requiring action appears. This group will convene within several hours to approve response strategy, review specific messaging and determine next steps.

Core Response Team:	Phone Numbers:	E-mail Address:
Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Donna Passero	Office-908-277-8335 Cell-908-803-9346 Home-973-394-0052	donna.passero@crbard.com
Chris Ganser	Office-908-277-9338 Cell-908-568-9411 Fax-908-277-8087	christopher.ganser@crbard.com
Doug Uelmen	Office-480-303-2629 [redacted]	doug.uelmen@crbard.com
John McDermott	Office: 480-303-2673 Cell: 602-684-7309	john.mcdermott@crbard.com
Rob Carr	Office: 480-303-2684 Cell: 480-220-2322	robert.carr@crbard.com
Brian Berry	[redacted]	brian.berry@crbard.com
Adjunct – John Lehmann, MD	Office-617-489-7080 Cell-508-341-8942 Home-508-358-5365	jlehmann@lehmannthomas.com
Frank Mankewicz	Office-202-944-5141 Cell-202-258-9020 Home-202-462-7202	fmankiewicz@hillandknowlton.com
Lee Lynch	Office-202-944-5186 Cell-571-214-8799	llynch@hillandknowlton.com
Kimberly Ocampo	Office-202-944-1905 Cell-202-997-4420	kocampo@hillandknowlton.com

CRT Conference Calls
The following telephone line is available 24 hours a day, seven days a week for the CRT to use for conference calls.

- Toll Free Dial-In Number: 1-888-453-5732
- Participant Passcode: 500965

V. Recovery Vena Cava Filter Audience Outreach Team

Depending on the situation, the CRT may determine that there is a critical need to contact other key audiences outside of this immediate response group. To facilitate effective and efficient communications among the various company divisions and appropriate external audiences, a point-of-contact has been designated to conduct this outreach. They are:

Audience Outreach Team:	Phone Numbers:	E-mail Address:
Additional Media: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
CEO and Board of Directors: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Recovery Filter Field Sales Reps: Janet Hudnall Carol Stone	Janet: Office-480-303-2630 Cell-602-881-1331 Carol: Office-908-277-8301 Cell-908-507-6574 Home-908-526-5579	janet.hudnall@crbard.com carol.stone@crbard.com
Recovery Filter Physicians: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Customers and Field Reps: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
All Other Employees: Diana McHugh	Office-908-277-8191 Cell-908-571-2841 Home-908-835-0107	diana.mchugh@crbard.com
Suppliers/Operations: Frank Maloit	Office-908-277-8177 Cell-908-528-3537 Home-610-330-9082 Home-781-837-9530	frank.maloit@crbard.com
Shareholders and Wall Street: Eric Shick	Office-908-277-8413 Cell-908-256-4238 Office- 908-277-8265	eric.shick@crbard.com

VI. Top Media Interview Dos and Don'ts

Following is a list of general dos and don'ts for interviews with major top media outlets.

Dos

- Offer a physician spokesperson for comment.
- Offer a researcher, patient or corporate executive for further insight.
- Offer medical studies validating Recovery Vena Cava Filters or retrievable vena cava filters in general.
- Ask for a list of questions, parameters of the story and permission to record your own video of the interview or any interviews with Bard employees, patients or physicians.
- Offer video of Bard's headquarters, if you already have a tape available.
- Manage the story. Draw the line at non-company spokespersons, "trial witnesses", salespersons, product designers, etc.
- Stay focused on the success rate and clinical effectiveness of the products, rather than the claims. Stick to your key messages.
- Include day-before and day-of key audience notification in your communications strategy. Assume key audiences such as employees, physicians, shareholders, customers and field sales reps will see the story. Be prepared to notify them about when the segment will air or has just aired, and provide a clear, convincing cover letter with your key messages, as well as a breakdown of comments made in the story matched with corresponding facts.

Don'ts

- Play favorites with the members of the media.
- Answer a question with "No Comment."
- Don't try to minimize the problem.
- Don't release sensitive or proprietary information.

VII. External Allies/Experts

Physician Spokespeople
If a reporter calls for comment, Bard should have reputable physicians confirmed to participate in interviews to attest to the product's success rate and the value it provides to patients.

The below physician has been identified to serve as a spokesperson who can speak to the value of the filter.

Gary S. Cohen, MD.
Chief, Interventional Radiology
Temple University Medical Center
3401 N. Broad St.
Philadelphia, PA 19140
(215) 707-3951
cohenator@aol.com

Third Party Industry Organizations and Potential Allies
Board members and other prominent leaders from ally organizations may be able to lend their credibility to Bard by providing ally spokespersons who can speak to the value of the retrievable Recovery Vena Cava Filter products (or retrievable vena cava filters in general) and Bard's position as a leader both in terms of innovation and customer care/safety. Allies may include representatives from the following organizations:

- Society of Interventional Radiology
- Association for the Advancement of Medical Instrumentation
- Medical Device Manufacturers Association
- Society for Vascular Surgeons

We currently are researching whether these organizations would be willing to speak to the media if an inquiry arises. For regional or local media outlets, it may be necessary to provide local sources. As the scenario develops, we may work with other third-party associations to determine local spokespeople.

In addition, Bard may want to consider either securing the partnership of a general medical device or consumer organization that can speak broadly about the value of Bard's products for consumers, such as:

- The Medical Device Manufacturers Association
- Center for Consumer Affairs or
- American Council on Consumer Interests (ACCI)

Finally, another consideration is for Bard to create a third-party organization that focuses on the enormous benefit of medical progress for consumers to override the negative perceptions created through a few (often frivolous) lawsuits.

VIII. Key Studies

Two studies are available specific to the Recovery Filter.

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 (NA2)patients have died with filters in place of causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

[NEED ABSTRACTS FOR THE ABOVE AND ADDITIONAL HUMAN STUDIES]

Summaries of key medical studies highlighting the success rate of Bard's Recovery Vena Cava Filter products and other vena cava filters can be found in the appendix. We have produced three separate sections of summarized studies: one focuses on the success of (permanent) (NA3)vena cava filters in general; the second focuses on retrievable vena cava filters as a whole; and the third details studies on Bard's Recovery Vena Cava Filter specifically. These summaries will serve as handouts and references for the media.

IX. News Breakdown

There are many various forms a news story can take and often one precedes another. To understand how news stories are originally generated and often end up featured on weekly news magazine shows, an explanation of how the media generally works is provided below. Please note there are always exceptions to the standards.

Wires – Associated Press, Bloomberg, Dow Jones, Reuters
National Dailies – *USA Today, New York Times, Wall Street Journal*
Top Market Dailies – *Los Angeles Times, Boston Globe, Washington Post*
Trades – *The Gray Sheet, MDDI, Medical Device Litigation Reporter*
News Magazine – *U.S. News & World Report, Time, Newsweek*
Daily News Program – Dateline, World News Tonight
Weekly News Program – 60 Minutes, 60 Minutes II, 48 Hours Investigates, 20/20

Wires
Electronic wire services are the most immediate sources for breaking news. Wire stories have the most power in terms of garnering national attention and generating widespread coverage because they are "picked up" by all media outlets. Since these stories are published in real time, they are often very short and have limited third-party sources. Many times, these stories are updated continuously as the story develops throughout the day or week.

National and Top Market Dailies
Most newspapers subscribe to wire services and look to the wires to determine news assignments. While many leading papers run complete wire stories, often editors use a wire story as a starting point to develop the story with local tie-ins, such as the story's impact on the community or using local experts for attributions. As a side note, nearly all newspapers will immediately post full wire stories on their Web sites.

Trade Publications
The trade journals are very influential in the medical device industry and will certainly be read by Bard's competitors. They will cover the issue in-depth and may discuss its impact on the entire industry. Trade coverage may also lead to more general coverage.

News Magazines
News magazines will typically develop a story based on an initial wire story, and/or news item in a top daily or trade publication. However, these publications will provide a much more in-depth analysis of the issue. They will conduct extensive research on the companies involved and the sources being used in the story. They dig deep and uncover information that is often under the radar. These stories can take weeks to develop.

Broadcast
As a general rule, broadcast follows print. Once the print story hits, broadcast interest in the story will likely escalate.

For daily broadcast segments, producers will either request an interview with a Bard spokesperson to take place at the local affiliate station or arrange for a video crew to come to Bard's headquarters. Broadcast segments on nightly news programs can take several days to develop.

Weekly programs like "60 Minutes" or "48 Hours" can take several weeks or even months to develop. Producers also will send a crew to the corporate headquarters to film the facility and interviews. They will likely make numerous trips to Bard's headquarters. They will conduct extensive interviews and ask pointed questions.

X. Newsmaker's Bill of Rights

As we respond to media inquiries and arrange interviews, remember that Bard has certain rights as newsmaker and reporters have their expectations.

1. The right to know the interview topic(s) in advance.
2. The right to know the identity and affiliation of the reporter.
3. The right to state your key points and, if appropriate, restate them.
4. The right to have some control over the interview environment.
5. The right to bring up relevant topics and points not specifically asked during questioning.
6. The right to know how the interview material is being used and whether others are being interviewed for the story.
7. The right to respond to accusations.
8. The right to correct misstatements and misinformation during an interview.
9. The right to restate obscure or lengthy questions.
10. The right to finish responses without interruption as long as your answer is concise and relevant.

Reporter's Expectations

1. Reasonable access to legitimate news sources.
2. Consideration of the reporter's deadline and logistical needs.
3. A timely response to an inquiry.
4. A concise and direct answer to a relevant question.
5. If available, printed or pictorial material to flesh out the interview information.
6. The availability of corporate spokespersons for follow-up inquiries, when necessary, for clarification.
7. Corrected information, if incorrect information is inadvertently given.
8. Proactive follow-up by newsmaker with new information or corrected information.
9. An opportunity to build an ongoing relationship.
10. The same kind of courtesy and respect that the newsmaker desires.

XI. Proactive Media Outreach

We do not recommend proactive outreach to media at this time. We believe that taking a low-key approach, in an effort to avoid drawing attention to the issue, is the most appropriate strategy.

XII. Step-by Step Management of Most Likely Scenarios

Note: If any of these scenarios occurs, H&K will immediately implement the Bard News Bureau, through which H&K's Bard Team members (Frank Mankiewicz, Lee Lynch, Kimberly Ocampo and Melissa Busse) will work with other members of H&K's Media/Crisis/Litigation team and CR Bard Vena Cava Core Team members to determine and implement strategy and media outreach.*

Scenario #1: Family of the deceased files a suit seeking damages from C. R. Bard. [LAW FIRM] issues a press release.

1. H&K will monitor any press announcements made by the plaintiff's law firm, as once a press release is issued, it may generate news coverage.
2. If a press release runs on the wire, H&K will send an email to the Core Response Team. The email will include the press release and any other relevant information. H&K will also call Holly Glass, Janet Hudnall and Donna Passero with this information.
3. H&K will immediately begin to monitor for any resulting press coverage.
4. As soon as press coverage begins to appear, we will activate the CRT:
   a. H&K will send e-mails to the CRT, including press coverage to date if available and a scheduled conference call time.
   b. H&K will follow up with phone calls to all CRT members, informing each member of the upcoming conference call.
   c. During the call, CRT members will agree on media strategy and responses. Strategy may include contacting reporters responsible for coverage and providing them with summarized studies and a statement based on approved key messages from the company.
   d. As determined, CRT members may be responsible for informing Audience Outreach Team members.
5. H&K will continue to monitor for additional coverage.

Scenario #2: A reporter calls Bard for comment.

1. The media inquiry comes in to Holly Glass.
2. Holly will notify Lee Lynch at H&K.
3. Depending upon the size and reach of the news outlet, either H&K or Holly Glass will call the reporter to find more information about the type of questions he or she may ask.
4. H&K will provide, through e-mail to the CRT, the list of anticipated questions and a time for a strategy conference. H&K also will gather and distribute to the team as much information as possible about the reporter.
5. H&K will follow up with phone calls to all CRT members, informing each member of the conference call.
6. During the call, the CRT members will agree on media responses.
7. As determined, CRT members may be responsible for contacting Audience Outreach Team members to inform them of the interview and pending coverage.
8. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
9. H&K will follow up with the reporter as necessary.
10. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
11. H&K will monitor for resulting and additional coverage.

Scenario #3: Filter migration or bariatric surgery (see example of recent negative story in appendix), in general, gets negative media coverage without singling out Bard or the Recovery Filter.

1. H&K will research the background of the reporters writing the negative stories and will forward this information, along with copies of the articles, to Holly Glass.
2. Holly Glass and H&K will determine the appropriate response (if any) on a case-by-case basis. Response may include the development of a letter-to-the-editor, pitching a "reactive" or follow-up interview to reporters in an effort to preempt any negative stories being written about Bard and its filter product and/or to help position Bard as a leader in this category.
3. If the scenario requires the development of a letter-to-the-editor, H&K will tailor the attached template, as required, and will forward the draft to all CRT members for review and approval.
    a. H&K will contact all CRT members to set up a time for a conference call.
    b. During the conference call, the CRT will review, edit and approve the letter.
    c. If the letter will be signed by a physician, H&K and Holly Glass will work to secure the physician spokesperson's approval and forward an edited version to the CRT for final review.
    d. H&K will forward the letter to the appropriate editorial contacts and monitor for coverage.
4. If the scenario requires an interview, H&K will provide Holly Glass with quick "refresher" course on media coaching tips and techniques.
    a. Holly Glass, H&K and the Audience Outreach Team will determine the appropriate messages and communications vehicle to inform Bard's key constituents prior to the airing of the program.
    b. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
    c. H&K will follow up with the reporter as necessary. H&K may arrange a follow-up interview with the physician spokesperson and/or a patient, as determined if necessary.
    d. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
    e. H&K will monitor for resulting and additional coverage.

Scenario #4 – News Bureau – A major news story breaks about the lawsuit and the "snow ball" effect kicks in, generating much negative media coverage on Bard and the Recovery Vena Cava Filter.

If this scenario occurs, H&K will immediately implement its Bard News Bureau to respond to all incoming media inquiries efficiently and effectively.

Media Contact Lists

H&K has identified the most likely reporters to write stories on lawsuits, based on past research for the mesh hernia repair product crisis plan. We have also identified the following:

- Legal and healthcare beat reporters at the wire services, top 25 daily newspapers and top financial news outlets
- Editors at health and medical device trade publications
- Editorial board contacts at the top 25 dailies, should Bard want to proactively secure background meetings with these influential reporters
- News directors at the major networks broadcast affiliates (NBC, ABC, CBS, and Fox) in Bard's key markets relating to the investigation (presently, Miami, FL and Grand Rapids, MI)

Following this document are the identified media outlets.

Toll-Free Line for Reporters

When and if necessary, Bard may consider activating a toll-free number, manned by appointed, trained persons to take messages of all incoming media inquiries. H&K can implement this phone line within hours.

Call Reports

As media inquiries come in, H&K will format all information regarding incoming media calls into call reports and submit these reports to Holly Glass. These reports will include the date and time of the initial inquiry, the name of the reporter, his/her publication, beat, purpose of call, questions he/she may have and dates and times of interview request. H&K will also gather as much information about each reporter as is available.

Prepared Statements

Depending on the amount of media inquiries and the rate at which they come in, it may be necessary to distribute a previously prepared statement. A sample statement has been created and approved by legal counsel. This statement reflects Bard's inability to comment on pending litigation and reinforces the need for approved key messages. It can be easily modified to address specific inquiries from media or new developments in pending cases.

If it is necessary, Bard may issue the prepared statement on PR Newswire. H&K has an existing account with PR Newswire already established.

The statement may be updated as Bard develops its position or as new information is gathered and actions are taken.

News Monitoring

H&K will continue to conduct daily monitoring for any stories related to litigation. For wire and print stories, H&K uses the Factiva Database, for online stories, H&K searches Google and Google News, and for broadcast stories, H&K works with VMS. VMS is monitoring nationally, but placing extra emphasis on markets where incidents are under investigation. H&K will prepare a report assessing the news coverage on a daily basis during the crisis situation, or as necessary.

News Evaluation

After the media coverage is generated and interest has dwindled, H&K will critique the coverage and provide an overall analysis of the scenario and make specific recommendations.

News Conference

In most situations, news conferences are neither necessary nor desirable. However, Bard should be prepared to move forward quickly with a news conference if deemed necessary. Holding a news conference should be considered when:

- ⇒ Written or electronic dissemination of a statement will not satisfy the media covering the situation.
- ⇒ The situation is extremely serious and media requests have reached a level or volume when they no longer can be handled through individual telephone calls.
- ⇒ Company actions can be best explained through a news conference that reaches all media at the same time with information, personal statements and visual documentation.

The major disadvantage to holding a news conference is that the forum allows for rigorous and potentially damaging questioning. News conferences can require intense preparation for the spokesperson and the CRT, including further message development, question anticipation and spokesperson training.

H&K will coordinate all logistics, including announcement, location, time, audio/visual equipment.

1. Announcement: H&K will draft the news conference announcement and distribute it across PR Newswire. The announcement will mention the issue, and list the spokesperson, time, location and contact for further information. Pending on the scope of the situation, this information may also be posted on Bard's Web site. Following the distribution of the announcement, H&K will follow up with telephone calls to obtain a preliminary headcount and identify key reporters.

2. Location: The location will be convenient for reporters and Bard executives. There will be a separate entrance and exit for the spokesperson, so he/she is not forced to wind through rows of reporters to get to the podium or to exit the facility.

3. Audio Visual Equipment: H&K will coordinate the rental or usage of all a/v equipment, including a podium, microphones, video camera, etc. Bard should tape the conference for its own records.

4. Materials: Bard press kits will be made available to all attendees, containing all collateral materials including fact sheets, recent press releases and executive biographies.

5. Agenda: H&K will develop a specific agenda for the news conference. The spokesperson will note the agenda and the specified timeline of the event.

6. Outside speakers: As the situation is evaluated, H&K may advise having a physician or third-party organization (industry) spokesperson available to answer specific medical-related questions.

Scenario #5 – News Bureau – Another negative migration case causes Bard to remove the Recovery Filter from the market.

1. Janet Hudnall contacts Holly Glass, who notifies H&K.
2. H&K immediately begins to monitor for news, coordinate a CRT conference call and prepare for roll out of News Bureau activities.
3. During the call, Donna Passero talks the CRT through the product recall process. The CRT determines the appropriate strategy, messaging and next steps.
4. Following the call, H&K provides the action items resulting from the call and an outline of CRT members' roles and responsibilities.
5. In conjunction with Holly Glass, H&K will draft all tactical plans and response materials, including initial statement customized according to audience (e.g., media, Wall Street, Bard employees, sales force, customers and physicians).
6. H&K coordinates follow-up call with both CRT and Audience Outreach Team to review materials and secure approval.
7. Audience Outreach Team notifies its appropriate target audiences.
8. H&K and Holly Glass activate the News Bureau, as outlined above in Scenario #3.

Scenario #6 – A competitor tips off media.
Any of the above scenarios may play out.

Recall?

XIII. H&K Team Contact Information

Frank Mankiewicz – Senior Counselor
Office: 202-944-5104
Cell: 202-258-9020
Home: 202-462-7202
Assistant: Laurel Laidlaw – 202-944-5141

Lee Lynch – Account Management
Office: 202-944-5186
Cell: 571-214-8799
Home: 703-823-3926

Kimberly Ocampo – Media Specialist and Key Support
Office-202-944-5193
Cell-917-584-7961
Home-202-248-2337

Melissa Busse – Key support
Office-202-944-3365
Cell-703-786-9423
Home-703-465-9619

Appendix

A. Key Messages – Recovery Vena Cava Filter: General Messages

1. The Recovery Vena Cava Filter, a Bard Peripheral Vascular product, is a well designed and tested inferior vena cava (IVC) filter that, when properly placed and intact, helps to reduce or prevent the risk of blood clots traveling to the lungs or heart.
   - [NAM]The Recovery Vena Cava Filter is indicated for use as both a permanent and retrievable device to reduce and prevent any blood clots from the legs that may break off and travel, or "migrate", through the bloodstream to the lungs or heart.

2. The Recovery Vena Cava Filter is proven in its safety and efficacy.
   - A properly placed filter can resist the force of a fair amount of blood clot; however, large clots and the forces of exertions, such as bowel movements, can overwhelm *any* filter's retentive capability, resulting in possible migration. *This is true for all IVC filters.*
   - Estimates based on available data suggest that these types of events are not occuring with excess frequency when compared with other vena cava filters.

3. The retrievability of the device is valuable and appealing from a clinical perspective to medical professionals and patients.
   - Retrievable filters are designed to be removed once the risk of pulmonary embolism has subsided.
   - The actual filter mechanism works exactly the same in retrievable and non-retrievable filters. Non-retrievable filters cannot be easily removed without injury to the patient.

4. At Bard, our number one priority is our commitment to our patients.
   - With any report of an adverse event, we take an immediate, systematic approach and form a multi-disciplinary team to thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take our responsibility to patients very seriously.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

B. Key Messages:

Specific to Miami Incident:

1. We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to our patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - [NAG] The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
   - [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.]

If asked about the Grand Rapids, MI incident in the course of these messages, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the Recovery filter on sales hold while conducting initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NAG] [NEEDS TO INCLUDE [illegible]]

Specific to the Grand Rapids, MI Incident:

1. We have been notified of the death of a patient whose medical treatment in Grand Rapids, MI included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to our patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - The Recovery filter was on sales hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NAS] [redacted]

If asked about the Miami Incident in the course of these messages, use the following statement: We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard's Recovery Vena Cava Filter. A multi-disciplinary team is thoroughly investigating the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:

- The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
- [NAS]The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
- [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.].

If Asked About Both Incidents:

1. We have been notified of two recent, unrelated incidences. One occurred in Miami, the other in Grand Rapids, MI. We have very few details that can be discussed at this point about the Grand Rapids incident. The Miami incident involved the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - [NA1q]The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
   - [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.].

If asked specifically for more information about the Grand Rapids, MI incident, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the product on sales hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NA1q]
[NEED TO INCLUDE CONCLUSIONS FROM [redacted]]

C. Draft General Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

As a physician who has implanted more than [NUMBER] Recovery Filters, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product. In actual practice and in reported studies, this life-saving clot-trapping device has been proven to be safe and effective when a patient's condition indicates a vena caval filter: thrombo-embolic disease (TED) with contraindication for anticoagulation, failure of anticoagulation, massive pulmonary embolism, or chronic, recurrent pulmonary embolism.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

As a physician[NA13], and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. In my experience, I have been able to safely remove the device once the risk of pulmonary embolism has been reduced.

Sincerely,

Physician's Name
Medical Facility
City

D. Draft Miami Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of pulmonary embolism has been reduced.

As a physician[NAIS], and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City

E. Draft Grand Rapids Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal..

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of embolism has been reduced.

As a physician, and a trainer of other physicians who implant and retrieve Recovery Filters,. I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City

F. Media Lists

H&K has identified medical/health and legal/litigation reporters and editorial board contacts at the following outlets:

Wires

- Associated Press
- Bloomberg
- Copley
- Cox
- Dow Jones
- Gannett
- Knight Ridder
- McClatchy
- Newhouse
- Reuters
- Scripps Howard
- Times
- Tribune
- UPI
- Universal Press Syndicate

Top Dailies

- *The Wall Street Journal*
- *USA Today*
- *The New York Times*
- *Los Angeles Times*
- *The Washington Post*
- *Daily News* (New York)
- *Chicago Tribune*
- *Newsday*
- *New York Post*
- *Houston Chronicle*
- *Chicago Sun-Times*
- *Chicago Tribune*
- *San Francisco Chronicle*
- *The Boston Globe*
- *The Boston Herald*
- *The Dallas Morning News*
- *Miami Herald*
- *The Arizona Republic*
- *The Atlanta Constitution*
- *The Philadelphia Inquirer*
- *The Star-Ledger* (Newark)

- *Star-Tribune* (Minneapolis)
- *Detroit Free Press*
- *The Plain Dealer*
- *Rocky Mountain News*
- *Denver Post*
- *Austin Statesman*
- *Austin Business Journal*
- *[PLACEHOLDER FOR MAJOR PRINT OUTLETS IN AND NEAR GRAND RAPIDS, MI]*

Medical/Health and Legal/Litigation Reporters at Top Financial Outlets

- Bloomberg (print and broadcast)
- *BusinessWeek* and Businessweek.com
- CNBC
- CNNfn
- Dow Jones
- *Financial Times*
- *Forbes*
- *Fortune*
- *Investor's Business Daily*
- *SmartMoney*
- The Street.Com

Editors at Relevant Medical, Health and Medical Device Publications

- *The BBI Newsletter*
- *Biomedical Instrumentation & Technology*
- *Biomedical Safety & Standards*
- *BNA'S Health Law Reporter*
- *Clinica World Device and Diagnostic News*
- *Diagnostic Insight*
- *The Gray Sheet*
- *Health News Daily*
- *In Vivo*
- *The Healthcare News*
- *Medical Device and Diagnostics Industry*
- *Medical Device Daily*
- *Medical Devices and Surgical Technology Week*
- *Medical Product Manufacturing News*
- *Medical Device Litigation Reporter*

News directors at the major networks broadcast affiliates in Bard's key markets

New York/New Jersey
- WABC-TV (ABC)
- WCBS-TV (CBS)
- WNBC-TV (NBC)
- WNYW-TV (FOX)

Miami
- WPLG-TV (ABC)
- WFOR-TV (CBS)
- WTVJ-TV (NBC)
- WSVN-TV (FOX)

Phoenix/Tempe
- KNXV-TV (ABC)
- KPHO-TV (CBS)
- KPNX-TV (NBC)
- KSAZ-TV (FOX)

[PLACEHOLDER FOR MAJOR BROADCAST OUTLETS IN AND NEAR GRAND RAPIDS, MI]

G. Recent Sample Article: Bariatric Surgery in General

04/11/2004 04:19:17
As Obesity Surgeries Soar, So Do Safety, Cost Concerns
Rob Stein, Washington Post Staff Writer

Source: *The Washington Post*
Date: April 11, 2004
Section: A Section
Page: A01

The number of overweight Americans resorting to stomach-shrinking surgery is rising so rapidly that health experts and insurance companies are increasingly becoming alarmed about the safety, effectiveness and mounting costs of the operations.

While the operations can produce dramatic benefits for very obese people, some hospitals and surgeons may be rushing too quickly to satisfy the surging demand, offering the lucrative procedures without adequate training, experience and support, experts say.

At the same time, the operations, which force people to eat less by reducing the size of their stomachs, are being performed too commonly on people who might be able to lose weight through diet and exercise, particularly younger adults and teenagers, they say.

Alarm has intensified because of scattered reports of severe complications and deaths around the country. In Massachusetts, for example, a special panel has begun assessing the procedure for state health authorities after several patients died following surgeries.

Citing uncertainty about the safety of the procedures and lingering questions about their long-term effectiveness, a growing number of insurance companies have begun balking at paying for the operations, which cost the nation close to $3 billion a year.

To try to resolve some of these issues, the National Institutes of Health has launched a five-year, $15 million research project to gather data about the operations, identify patients most likely to benefit and learn more about how they work.

In the meantime, the American Society for Bariatric Surgery, which represents surgeons who perform the procedures, has established an independent nonprofit corporation that in June will begin identifying "centers of excellence" deemed most qualified to do the complicated operations. The group is also gathering scientists at Georgetown University next month in the hopes of reaching a consensus on the risks and benefits of the treatment.

The rising concerns about stomach surgery illustrate the uncertainties that can occur with the emergence and proliferation of new surgical procedures, which often do not undergo the same level of testing, scrutiny and government oversight as new drugs or medical devices.

In addition, the debate over whether insurers should pay for the surgery illustrates the tension that is mounting as the obesity epidemic adds billions of dollars to the nation's medical bill. Millions of Americans already meet the criteria for the operation, which costs about $25,000, and millions more are expected to join those ranks as obesity rates soar.

"Insurance companies are feeling the first pressure of the increasing costs of the rising obesity epidemic from this procedure," said Roland Sturm, who studies the economic impact of obesity for the Rand Corp., a private research organization. "If we look into the future, the rising obesity epidemic will continue to have tremendous effects on health care costs. It's an astonishingly big factor. And it's only going to get bigger."

As the number of obese Americans has soared and new, less invasive laparoscopic versions of stomach surgery have been introduced, the number of people undergoing the operations has skyrocketed, spurred by the lack of effective alternatives and by celebrity patients such as NBC's "Today" show weatherman Al Roker. The number of surgeries shot up from about 16,000 a year in the early 1990s to an estimated 103,000 in 2003 -- and is expected to approach 150,000 this year, making it one of the fastest-growing procedures. Many centers report long waiting lists.

Surgeons perform several variations, but all involve sharply restricting the size of the stomach, either by stapling most of it closed or sealing it off with elastic bands and bypassing portions of the digestive system to reduce the number of calories that can be absorbed. The procedures can enable severely obese people to lose hundreds of pounds, alleviating disabilities and preventing, even sometimes reversing, serious health problems, most notably diabetes and high blood pressure.

But the operations are complicated, and patients are prone to life-threatening complications, including bleeding, blood clots, leakages and infections. Even if they have no serious complications, patients often experience unpleasant side effects, including a phenomenon known as "dumping" -- nausea, vomiting and diarrhea -- when they overeat. As a result, patients have to undergo intensive counseling and monitoring to make sure they eat appropriately and do not suffer nutritional deficiencies.

"It's extremely difficult surgery," said Paul Ernsberger, an associate professor of nutrition at Case Western Reserve University. "Even when it's done perfectly, there can be a lot of problems."

According to federal guidelines issued in 1991, the procedure is supposed to be performed only on people who are at least 100 pounds overweight -- and primarily on those who are also suffering severe health problems because of their weight. While most people getting the procedure probably meet those criteria, there is concern that increasing numbers of people who weigh less are also undergoing the procedure.

"Many people who are not morbidly obese are trying to get this procedure. It's rapidly viewed as the answer to obesity, and more and more say, 'I can get surgery done as an answer to my problem,' " said Barry Schwartz of Blue Cross and Blue Shield of Florida. "We've actually seen a couple of patients who decided with their doctor that they would eat more so they could qualify. It's perverse."

Schwartz and other critics say the surge in popularity is enticing some hospitals and surgeons to try to capitalize on the interest.

"Many hospitals and physicians see this as a cash cow," Schwartz said. "We've seen surgeons who did a weekend course and then started doing this high-risk surgery. Make no mistake about this: This is high-risk surgery. The quality of service is going down, and the risk to patients is going up."

Some researchers also question the reliability of the data on the safety and effectiveness of the procedures.

"We don't have quality longer-term studies that give us good data on long-term safety and effectiveness," said Frank Lefevre, an associate professor of medicine at Northwestern University who evaluated the procedures for the Blue Cross and Blue Shield Association.

Already alarmed by skyrocketing health costs overall, a number of insurers, including Blue Cross and Blue Shield of Florida and Nebraska and Humana Inc., are discontinuing coverage for the operations.

"We've had an explosion in obesity and an explosion in the demand for quick fixes, if you will, to the problem of obesity," said Helen Darling, president of the National Business Group of Health, which represents major corporations on health issues. "It's beginning to dawn on insurance companies and employers that even after the surgery, there are a lot of big expenses and a lifetime of care. Many employers and insurance companies feel this is just not affordable today."

Some experts liken the situation to what happened with bone marrow transplants for breast cancer in the 1990s, when terminally ill breast cancer patients clamored for the procedure until carefully designed studies finally showed it did not save lives.

"Whenever a new technique seems to be providing benefit, it tends to proliferate," said Jonathan Moreno, a University of Virginia bioethicist who studies surgical procedures. "Oftentimes, these things gradually become the standard of care without going through any studies."

Proponents of the surgery say the procedures have undergone extensive study and have been clearly shown to help patients, enabling many to shed one-third to one-half of their excess body weight or more and keep it off for many years.

"I think these insurance companies may be using this as an excuse to avoid their responsibility. They think they can get away with this because of the prejudice that's out there for people who are obese," said Harvey Sugerman, president of the American Society for Bariatric Surgery. "I think it's a travesty."

For patients who have been suffering for years and been unable to lose weight despite repeated diets and exercise regimens, the operations are life-altering, he said. "It's an amazing operation. It's hard to describe how helpful it is to these patients. You have a patient who comes in who can hardly breathe, their legs are all swollen up, they have diabetes and high blood pressure, and they come back to you in three months, and they're all gone. They feel wonderful."

While the procedures can be dangerous, Sugerman and others said that for appropriate patients, the benefits clearly offset the risks, which are on a par with the dangers of operations for other life-threatening conditions involving seriously ill patients.

"It's actually surprising how good the results are," said David R. Flum, a University of Washington surgeon. "If you look at all the options available for the treatment of obesity, we know one thing for sure: Nonsurgical approaches, even the most radical approaches, even the most aggressive nonsurgical approaches, are horribly ineffective."

But Flum and some other experts acknowledge the complication rates are unclear. Most published studies have involved highly experienced surgeons operating on ideal candidates. Some research indicates the complication and mortality risks may be much higher than reported, especially as less experienced surgeons begin performing the procedures on a wider spectrum of patients.

"We really don't know what's happening in the real world, and there's a lot of reason to be really worried about that," said Flum, who is helping evaluate the procedures for the NIH consortium. "In the real world, surgeons may do many fewer patients per year. They are learning the procedure. Or picking patients who may not do as well. A lot of things have got us worried."

http://www.washingtonpost.com

[NA1]"MCVI" is the more commonly known name for the group of physicians in Miami of which Dr. Powell, the filter implanting physician, is a part.
[NA2]No. The number is not 6 now. This is the data that is in the product's package insert (IFU). These facts still hold for the Canadian cohort.
[NA3]I'm not sure which papers are being referenced here (the first and second papers, specifically)
[NA4]I think this entire 1st sub-bullet is problematic. We don't know how many filter have been implanted; we only know how many we've sold. Also, "success" really depends on how you look at it. Does lack of complaints equal success?
[NA5]An IVC filter does not prevent blood clots; it just keeps it from traveling to the lungs.
[NA6]Do we want to add that this was at post-mortem?
[NA7]Probably need to add additional comments about the initial conclusions of this incident.
[NA8]Probably need to add additional comments about the initial conclusions of this incident.
[NA9]Include that this was at post-mortem?
[NA10]Include that this was at post-mortem?
[NA11]Probably need to add additional comments about the initial conclusions of this incident.
[NA12]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)
[NA13]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.
[NA14]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)
[NA15]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.
[NA16]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

Internal Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

Note: Internal Q&A to be used by approved Corporate spokespeople to respond consistently to inquiries from media. Not to be handed out externally to any audiences.

1. *What is the Recovery Vena Cava Filter and how does it work?*

   Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

   The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cava with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. *What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?*

   A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

   The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *What is the marketshare of the Recovery Filter for the overall vena cava filter market?*

   6% (in units) .

4. *What is the marketshare of the Recovery Filter for the retrievable vena cava filter market?*

   We have sold over 8,500 units of the Recovery Filter to date. We understand that the overall total market for all retrievable and non-retrievable vena cava filters is approximately130,000 units.

   While the retrievable segment of the vena cava filter market is rapidly growing, for the past 12-month period, the market is estimated to have been approximately 30,000 units. Of that, Recovery had a 25% share.

5. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

   [NA1] We have sold over 8,500 units of the Recovery Filter to date

6. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

   Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

   In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

   We are happy to provide a full listing of study summaries to you.

7. *What are pulmonary emboli and what are the risks associated with them?*

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

8. *Under what circumstances would the Recovery Vena Cava Filter be used?*

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated.
b. Failure of anticoagulant therapy for thromboembolic disease.
c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

9. *How is the Recovery Vena Cava Filter inserted?*

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

10. *Who designed the Recovery Filter?*

Bard purchased the product design and manufacturing from a valued partner. Bard has thoroughly assessed and tested the product and stands behind its design in every way.

11. What is the name of the company that designed the Recovery Filter?

That information can be found in public records.

12. Have there been any design changes in the Recover Filter over the years?

There have been changes in the delivery system but not the filter itself.

13. What level of expertise is required to properly insert the Recovery Vena Cava filter?

Physicians who have undergone training for minimally invasive, endovascular procedures can place the Recovery Vena Cava Filter. These physician specialties include, but are not limited to, interventional radiologists, vascular surgeons, trauma surgeons, cardiologists, and general surgeons as well as residents and fellows of those disciplines.

Placement of the Recovery Filter, in general, is quick (10 minutes) if there is easy access to the femoral vein. The procedure has been described by physicians as easy to perform.

14. How are doctors trained on the proper use of the Recovery Vena Cava filter? How extensive is this training?

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

15. What are the potential complications associated with the Recovery Vena Cava filter?

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

16. How often does the Recovery Filter actually migrate?

As of the end of April 2004, out of 8,500 devices sold in the U.S., there have been six reported cases of migration.

There is risk of migration with any vena cava filter. There is no single definitive cause of filter migration. The buildup of a large clot or series of clots, the movement of the walls of the vena cava due to respiration and improper filter placement can cause migration. There are also other factors that could potentially cause a filter to migrate, and many questions still remain as to exactly why filters migrate. In addition, filters may appear to have migrated due to x-ray equipment variation, patient position, measurement error, and respiration.

17. How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

18. Are retrievable filters more susceptible to migration than nonretrievable filters?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

19. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NA3]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

20. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

21. What are the dangers associated with filter migration?

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

22. If a retrievable filter provides the added benefit of retrievability and creates no greater risk of migration or other complications, why would any physician choose to use a non-retrievable filter?

I cannot speak on behalf of physicians but understand that non-retrievable filters can be less expensive than retrievable filters. Presumably, if a physician believes there will be no reason to remove the filter, it might make sense to choose the less expensive non-retrievable option. However, there is no way to predict with 100% accuracy whether or not a patient is going to require the filter for the rest of his/her life. I understand though, that an increasing number of physicians choose retrievable over non-retrievable vena cava devices after gaining greater understanding of the safety, efficacy and added benefits of retrievable filters.

23. Migration of a Recovery Filter was recently listed as the cause of death for a patient in Miami. Can you tell us why this specific filter migrated?

As with any report of an adverse event, we took an immediate, systematic approach to determine the cause and events. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood

clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

24. If filter migration was not the cause of death, why was it listed as the cause of death on the coroner's report?

I cannot speak for the coroner. What I can tell you at this point, however, is that from the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

25. Is it possible that the filter was not inserted properly?

I do not want to speculate on the role of filter placement in this incident. What I can say is that, while improper filter insertion or placement can cause migration, we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

26. Is there any reason to believe that the Recovery Filter is to blame for this patient's death?

I do not want to speculate on the role of the Recovery Filter in this incident. What I can say is that we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

27. Has Bard been sued by the family of the deceased?

Not to my knowledge.

28. *Has the Recovery Filter been associated with other deaths in the past?*

Yes. A patient in Lacrosse, Wisconsin died with a Recovery Filter in place. The cause of death cited was pulmonary embolism.

29. *Has Bard been sued because of death or damage caused by migration in the past?*

Not to my knowledge.

30. *In the late 80's, weren't Bard's balloon angioplasty medical devices permanently pulled from the market because of safety issues?*

The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community and had nothing to do with the situation you mentioned. In the late 1980s, a C.R. Bard subsidiary named USCI manufactured balloon angioplasty catheters, which were taken off the market. The details of criminal and civil lawsuits associated with these catheters are well documented. USCI was sold and no individual involved in those incidents is currently with the company. Since then, the entire executive management team has been changed. Today, Bard maintains an excellent working relationship with the FDA.

31. *What other Bard products have been pulled from the market and for what reasons?*

Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies to our patients. Holds can occur for a variety of safety and non-safety related reasons. In cases in which safety was a concern, products were placed back on the market after further testing. The Recovery Vena Cava Filter products we are discussing today are considered extremely safe and effective by the medical community.

32. *What Bard products have been put on hold in the past two years?*

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

33. *Have you pulled any products over the past five years that have not been put back on the market? If yes, why were they pulled?*

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

34. *How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?*

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

35. *Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?*

John A. Kaufman, MD [2]
Anthony C. Venbrux, MD [7]
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

36. *Appropriate question must be developed and addressed regarding MAUDE database. Space holder question: Can you explain the data in the FDA's MAUDE database for the Recovery Filter as compared to other vena cava filters?*

[PLEASE PROVIDE]

[NA1]It is impossible to determine the number of filters that have actually been placed. The only data point that we can provide is the number that have been sold.
[NA2]Again, this is difficult to determine. All we know is how many have been sold. Also, does lack of complaints mean that it was safely used?
[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.
[NA4]This is not necessarily true.

External Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

[Note: External Q&A are intended to be used by Bard Core and Audience Response Team members to consistently respond to questions from external audiences, and can be handed out to media, customers, physicians, suppliers, investors and other Bard audiences.]

1. *What is the Recovery Vena Ceva Filter and how does it work?*

   Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

   The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cavae with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. *What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?*

   A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

   The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

We have sold over 8,500 units of the Recovery Filter to date

4. *Under what circumstances would the Recovery Vena Cava Filter be used?*

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated.
b. Failure of anticoagulant therapy for thromboembolic disease.
c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

5. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

We are happy to provide a full listing of study summaries to you.

6. *What are pulmonary emboli?*

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

7. *How is the Recovery Vena Cava Filter inserted?*

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

8. *Have there been any design changes in the Recover Filter over the years?*

There have been changes in the delivery system but not the filter itself.

9. *How are medical professionals trained on the proper use of the Recovery Vena Cava filter?*

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

10. *Are there potential complications associated with vena cava filters?*

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

11. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

12. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NA2]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

14. Is CR Bard currently involved in any lawsuits surrounding the Recovery Vena Cava filter?

No

15. Has Bard been sued because of death or damage caused by migration of a Recovery Vena Cava Filter in the past?

No

16. How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

17. Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?

John A. Kaufman, MD
Anthony C. Venbrux, MD
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

[NA1]Impossible to know how many have been placed. We have sold over 8500 as of the end of April.
[NA2]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.
[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

EXHIBIT 12

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 13

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 14

To Plaintiffs' Response to Bard's Motion for Protective Order

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona October 29, 2015

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

SCHEDULING CONFERENCE

Official Court Reporter:
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Sandra Day O'Connor U.S. Courthouse, Ste. 312
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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

business to jump into discovery on what might become spoliation issues.

No matter when we do it, the new Rule 37(e) that's becoming effective on December 1 is going to govern what steps I take.

What I'm inclined to do with this issue is since I'm thinking we ought to have at least two phases in the discovery, not try to do anything on this in the first phase, get through the additional ESI discussions you all are going to have, and then at a relatively close case management conference talk about exactly what we think needs to be done on that issue. But I'm not thinking we need to slay this dragon now. What do you all think?

MR. STOLLER: Your Honor, I think that makes sense and I think a lot of this will get teased out, for a lack of a better term, between back and forth with the plaintiff and defense as we go over the ESI issues in general.

MR. NORTH: Your Honor, I think that makes perfect sense. I want the Court to understand my client issued its first legal hold in December 2004 concerning this line of products and there had been legal holds in place. It may become an issue later down the line if those worked in a certain instant, but I believe the Court's proposal is agreeable.

THE COURT: What discovery issues have I missed?

MR. BOATMAN: Your Honor, I can only think of one. It's you didn't miss it, it wasn't in our submittal.

If the idea is there's certain discovery we have to do in Phase One to determine the scope of reopening prior depositions of work that's already been done, I think

EXHIBIT 15

To Plaintiffs' Response to Bard's Motion for Protective Order

Nelson Mullins

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November 20, 2015

VIA E-MAIL AND FEDERAL EXPRESS

Paul L. Stoller, Esq.
Gallagher & Kennedy
2575 E. Camelback Road
Suite 1100
Phoenix, AZ 85016

Re: ESI Issues

Dear Paul,

I am writing to further respond to your November 5, 2015, letter relating to ESI issues.

Architecture of Bard's IT Systems

In your letter, you very broadly request information relating to Bard's information systems and infrastructure.

I recently provided you the transcript of the 30(b)(6) deposition of John Olenoski, which addresses many of the topics you raised regarding Bard's IT systems. In connection with Mr. Olenoski's deposition in the women's health litigation, we produced an extensive amount of corporate-related IT policies and procedures. I have provided those to you, as well as the IT policies and procedures that were previously produced to members of the PSC. After reviewing the deposition and extensive material provided to you, please let me know if you have any remaining questions.

I also previously provided to you the letters we exchanged with Troy Brenes relating to shared drives and the Master Control System (formerly QUMAS) document control system, which John Olenoski addressed, to some extent, in his 30(b)(6) deposition. Over the years, we have also collected documents from these drives and systems in responding to discovery.

Bard Litigation Hold and Document Destruction Policies

Bard began issuing legal holds relating to the Bard IVC filter litigation in December 2004. Since that time, Bard has periodically updated those holds.

Again, I believe that the corporate policies and the 30(b)(6) deposition of John Olenoski that I have provided to you will answer most, if not all, of the questions you have raised regarding Bard litigation hold and retention policies. If you still have questions after reviewing that material, please let me know.

Bard's Collection Efforts/Reports

The first document collection relating to the Bard IVC filter litigation occurred in 2005 and included collection from over 70 custodians and also included collection of shared drives. The material was gathered by our firm without the use of an outside vendor. I am attaching a list of custodians for whom ESI was collected and produced from that collection.

Since that time, there have been additional collections and productions, including in 2010/2011 with the assistance of BIA, a discovery vendor. I am attaching a listing of the custodians for whom ESI was produced from that timeframe. BIA's ESI Report that I recently provided you includes a list of the "priority" custodians for whom ESI was produced in 2013. I am attaching that again for your convenience.

As part of our past productions to members of the PSC, we have previously provided file path information and custodian information as part of the produced metadata, so you should already have access to that information.

Bard's Methodology for Determining Responsiveness

As you know, we have used keyword terms throughout the history of the litigation to identify responsive documents. Those keyword terms were negotiated and agreed to with opposing counsel during the early phase of the litigation. Thereafter, we had significant negotiation and motion practice with the Lopez McHugh firm in the *Phillips* matter. I recently provided you with the background material relating to the ESI/keyword terms used.

Format of Production

After extensive negotiations and litigating the issues in the past, ESI has been produced in *.tiff image format, with the exception of electronic spreadsheets (e.g., Excel), electronic presentations (e.g., Powerpoint), and audio/video files, all of which were produced in native format, unless they were subject to redaction (e.g., for privilege or privacy information), in which case they were produced in *.tiff or a redacted native format.

Plaintiff ESI/Social Media

As to ESI and social media regarding the MDL plaintiffs, what has been done in the past and what is being done now to ensure that relevant ESI relating to the plaintiffs and their claims is being preserved, collected, and produced?

Have the plaintiffs been notified of their duties to preserve ESI? If so, when and in what manner were they notified?

Has anything been collected? If so, when? Also, what methodology and search process has been employed to collect potentially-relevant ESI? How has the location of potentially-relevant information identified?

In addition, what steps have been taken in the past and what steps are being taken now to ensure that potentially relevant social media (e.g., Facebook, Instagram, Twitter, YouTube, etc.) is being preserved, and what steps are plaintiffs taking going forward?

Sincerely,

Matthew B. Lerner

MBL:jbruner

Enclosures

EXHIBIT 16

To Plaintiffs' Response to Bard's Motion for Protective Order

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ANTHONY PAYNE, et al.,

Plaintiffs,

v. CASE NO. 6:11-cv-1582-Orl-37GJK

C.R. BARD, INC., et al.,

Defendants.

JACKSONVILLE DIVISION

LESSIE TILLMAN,

Plaintiff,

v. CASE NO. 3:13-cv-222-J-34JBT

C.R. BARD, INC., etc., et al.,

Defendants.

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ORDER

THIS CAUSE is before the Court upon Defendants' Motions for Protective Order ("Motions") in the above-styled cases. The Motions concern Defendants' efforts to prevent the discovery and use of a report prepared by Defendants' consultant, Dr. John Lehmann ("the Lehmann Report" or "Report").[1] These Motions have generated

[1] This Order discusses the substance of the Report in some depth. Until further order of the Court, the Court has redacted revelatory discussion of the Lehmann Report from the public version of this Order and will file an unredacted version under seal that the parties may access. Further, certain documents submitted by the parties for *in camera* inspection in connection with the Motions will be filed under seal but made available only to the Court. (*See Tillman* Doc. 79 at 2; *Payne* Doc. 142 at 2.)

numerous ancillary filings. For clarity's sake, the Court itemizes the filings under consideration below.

In *Tillman v. C.R. Bard, Inc.*, 3:13-cv-222-J-34JBT ("*Tillman*"):

1. Defendants' Motion for Protective Order (*Tillman* Doc. 29).

2. Plaintiff's Opposition to Defendants' Motion for Protective Order (*Tillman* Doc. 32).[2]

3. Defendants' Reply in Support of Motion for Protective Order (*Tillman* Doc. 36).

4. Plaintiff's Amended Sur-Reply to Defendants' Reply to Opposition of Motion for Protective Order (*Tillman* Doc. 46).[3]

5. Defendants' Notice of Filing Supplemental Authority in Support of their Motion for Protective Order (*Tillman* Doc. 49).

6. Plaintiff's Response to Defendants' Notice of Filing Supplemental Authority in Support of their Motion for Protective Order (*Tillman* Doc. 66).

In *Payne v. C.R. Bard, Inc.*, Case No. 6:11-cv-1582-Orl-37GJK ("*Payne*"):

1. Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion for Protective Order (*Payne* Doc. 68).

2. Plaintiffs' Verified Response Opposing Defendants' Motion for Protective Order (*Payne* Doc. 84).[4]

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[2] Certain exhibits to Plaintiff Tillman's Response have been separately filed under seal. Relevant portions of this document therefore also appear at *Tillman* Docs. 33 and 64.

[3] The *Tillman* Plaintiff attaches exhibits to certain filings, including to this one, that do not appear in any filing before the Court in the *Payne* case. However, they do not significantly impact the Court's decision. For all practical purposes, the relevant evidentiary records in both the *Payne* and *Tillman* cases are substantially identical.

[4] Certain exhibits to the *Payne* Plaintiffs' Response have also been separately filed under seal. Relevant portions of this document therefore also appear at *Payne* Doc. 79.

3. Defendants' Reply in Support of Motion for Protective Order (*Payne* Doc. 94).

4. Defendants' Notice of Filing Supplemental Authority in Support of Their Motion for Protective Order (*Payne* Doc. 110).

5. Plaintiffs' Notice of Joinder of Plaintiff, Lessie Tillman[]'s Response to Defendants' Notice of Filing Supplemental Authority in Support of their Motion for Protective Order, and Plaintiff's Objection to Defendants' Amended Motion for Leave to Supplement Record with Additional Evidence for In-Camera Inspection and Counter Proposal (*Payne* Doc. 128).

6. Defendants' Response to Plaintiff's Notice of Joinder of Plaintiff, Lessie Tillman's Response to Defendants' Notice of Filing Supplemental Authority in Support of their Motion for Protective Order, and Plaintiff's Objection to Defendants' Amended Motion for Leave to Supplement Record with Additional Evidence for In-Camera Inspection and Counter Proposal (*Payne* Doc. 134).

Payne and *Tillman* are two of several lawsuits that various plaintiffs around the country have brought against Defendants concerning the alleged failure of Defendants' medical device, the G2 Inferior Vena Cava Filter ("G2 IVC Filter"). The Lehmann Report analyzes the performance of the G2 IVC Filter's predecessor device, Defendants' Recovery Filter. The plaintiffs in several of these other cases have also sought to use the Lehmann Report. Defendants have resisted in each of them, arguing primarily that the Lehmann Report is protected work product and privileged attorney-client communication. Defendants make the same arguments here.

Accordingly, this is not the first time that a court has passed upon whether the Lehmann Report is properly shielded from discovery. The District of Nevada,[5] the

[5] *Phillips v. C.R. Bard, Inc.*, 290 F.R.D. 615, 660–61 (D. Nev. 2013).

Northern District of Ohio,[6] and an Arizona Superior Court[7] have held that the Lehmann Report is protected work product. A California Superior Court has decided against Defendants, however, and rejected their efforts to claw back the Lehmann Report after it was inadvertently disclosed in that litigation.[8] The California court denied Defendants' motion in a minute order, however, which contains no analysis, and therefore the grounds for this court's decision are ambiguous.

After the parties' exhaustive briefing and numerous evidentiary submissions, the Court concludes that Defendants have failed to carry their burden of showing that the Lehmann Report is protected as work product or as an attorney-client privileged communication. Accordingly, the Motions for Protective Order are due to be **DENIED**.[9]

I. Background

A. The *Payne* and *Tillman* Plaintiffs' Claims

Plaintiffs in both *Payne* and *Tillman* sue Defendants for the alleged failure of their G2 IVC Filters, a medical device that Defendants designed, manufactured, and marketed. According to the *Tillman* Amended Complaint, the G2 IVC Filter is designed to be implanted in a patient's inferior vena cava (*Tillman* Doc. 10 at 3), the large vein that carries deoxygenated blood from the lower part of the body back to the heart. If functioning

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[6] *Carr v. C.R. Bard, Inc.*, Case No. 3:13-cv-824, 2014 WL 463447 (N.D. Ohio Feb. 5, 2014).

[7] *Barkley v. C.R. Bard, Inc.*, Case No. CV 2011-02150 (Ariz. Sup. Ct. Feb. 27, 2014).

[8] *Giordano v. CR Bard Inc*, Case No. 37-2011-69363-CU-PO-EC (Cal. Sup. Ct. Apr. 10, 2013). This inadvertent disclosure is how the Report was obtained in many cases, including the cases at bar.

[9] The Court will not, however, award expenses to Plaintiffs because the Motions are substantially justified. *See* Fed. R. Civ. P. 26(c)(3) & 37(a)(5).

properly, the filter catches blood clots as they flow from the legs and pelvis to the heart and lungs, where they might otherwise cause pulmonary embolisms. (*Id.* at 3–4.)

Plaintiffs allege that their respective devices did not function properly. Tillman alleges that her device failed and migrated to her left renal vein, which branches off the inferior vena cava and carries blood from the left kidney. (*Id.* at 10.) This failure allegedly caused severe complications. According to Tillman's Amended Complaint, she underwent surgery on March 7, 2009 to remove the filter. But the operation was not successful and the device was not removed. (*Id.*)

Payne alleges similar results. He alleges that his filter also migrated to his left renal vein. (*Payne* Doc. 11 at 2–4.) Additionally, he alleges that his filter fractured and now lies "in a transverse position relative to the flow channel and is embedded into the caval wall." (*Id.* at 3) He alleges that his filter is "not amenable to removal and the Filter will remain in the Plaintiff permanently." (*Id.*)

Plaintiffs allege that Defendants knew or should have known that their G2 IVC Filter presented an undue risk of these kinds of complications due to defective design and manufacture. (*Tillman* Doc. 10 at 2–3; *Payne* Doc. 11 at 4.) Plaintiffs allege that Defendants brought the filter to market anyway and misrepresented its risks. (*Tillman* Doc. 10 at 3; *Payne* Doc. 11 at 4–7.) Payne sues Defendants for negligence, design defect, and manufacturing defect. (*Payne* Doc. 11 at 4–7.) Tillman sues under these theories and for failure to warn. (*Tillman* Docs. 10 at 12–20, 17 at 1.)

B. The Lehmann Report

In November 2004, Defendants hired Dr. John Lehmann [redacted]

[redacted]

[redacted][10]

[redacted]

[10] This is not the only time Defendants hired Dr. Lehmann. One of Defendant Bard Peripheral Vascular, Inc.'s senior employees, Dr. David Ciavarella, described Dr. Lehmann's role thus:

> John Lehmann is a physician, nonpracticing, who is a consulting medical director to Bard in particular during the time period between the retirement of Dr. Adwers and the time that I came on. However, he remained a consultant to various departments at Bard for quality and regulatory for a number of years.

(*Tillman* Doc. 64-3 at 39.)

[redacted]

[redacted]

C. The Instant Motions for Protective Order

In the instant Motions for Protective Order, Defendants ask the Court to order Plaintiffs to destroy any copies of the Lehmann Report in their possession and to prohibit Plaintiffs from using the Report in prosecuting their cases. (*Tillman* Doc. 29 at 2; *Payne* Doc. 68 at 2.) Defendants argue that the Report is protected by the work product doctrine and the attorney-client privilege. (*Tillman* Doc. 29 at 5–10; *Payne* Doc. 68 at 6–12.)

For evidentiary support, Defendants rely primarily on a February 12, 2013 affidavit by Donna Passero, Defendant C.R. Bard, Inc.'s ("CRB") assistant general counsel (*Tillman* Doc. 29-3; *Payne* Doc. 68-1) and record excerpts of an April 2, 2013 deposition of Dr. Lehmann, in which he discussed his work for Defendants (*Tillman* Doc. 57-1; *Payne* Doc. 121-1). Also, after the Motions were fully briefed, Defendants moved the Court to

consider *in camera* a November 2004 contract between Dr. Lehmann and Defendants, pursuant to which Defendants allege that Dr. Lehmann prepared the Report ("the November 2004 Contract"). The Court granted these motions and ordered Defendants to submit this November 2004 Contract for *in camera* review. (*Tillman* Doc. 79 at 3; *Payne* Doc. 142 at 3.) Also submitted were all other contracts between Defendants and Dr. Lehmann that the parties had in their possession covering the years 2003 through 2011.

In the affidavit, Passero states that she and CRB's law department retained Dr. Lehmann "for the purpose of providing outside consultation services to the Law Department regarding anticipated and ongoing product liability litigation." (*Tillman* Doc. 29-3 at 2; *Payne* Doc. 68-1 at 2.) Specifically, Passero says, "Dr. Lehmann was retained for the purpose of conducting an independent investigation and drafting a report concerning Bard's Recovery® Filter, which I -- in conjunction with Bard's Law Department -- requested for the purpose of providing Bard with legal advice concerning the Recovery® Filter and to prepare for and assist with anticipated and ongoing litigation." (*Tillman* Doc. 29-3 at 2–3; *Payne* Doc. 68-1 at 2–3.)

In keeping with the confidential nature of the Report, Passero told Dr. Lehmann "that the results of his investigation and his report should only be relayed to Bard's Law Department or to those whom Bard's Law Department may direct." (*Tillman* Doc. 29-3 at 3; *Payne* Doc. 68-1 at 3.) During the course of the investigation, "Dr. Lehmann communicated with a small and limited number of Bard employees for the purpose of obtaining and providing information in order to fulfill his duties pursuant to the contract he signed with Bard's Law Department." (*Tillman* Doc. 29-3 at 3; *Payne* Doc. 68-1 at 3.) According to the Passero Affidavit, distribution of the final Report was also limited. The

Report initially went to Passero, who distributed it to only five Bard employees, one of whom was a member of the law department. These individuals all "had instructions that the report and associated materials were confidential and that any further distribution of the report should be limited to only those employees or consultants who need the report to perform their proper job functions." (*Tillman* Doc. 29-3 at 3; *Payne* Doc. 68-1 at 3.)

In Defendants' excerpts of Dr. Lehmann's deposition, Dr. Lehmann testified that "Bard asked me to do legal consulting for them in fall of 2004 . . . . regarding advice about potential litigation related to the Recovery Filter." (*Tillman* Doc. 57-1 at 3; *Payne* Doc. 121-1 at 2.) There is no mention of actual litigation pending at that time. Dr. Lehmann testified that he had "two consulting contracts with Bard in 2004." (*Tillman* Doc. 57-1 at 4; *Payne* Doc. 121-1 at 3.) Dr. Lehmann continued: "One was general consulting, which I think covered everything but the specific activities related to the legal consulting that I did." (*Tillman* Doc. 57-1 at 4; *Payne* Doc. 121-1 at 3.) He received the legal consulting assignment from Ms. Passero. (*Tillman* Doc. 57-1 at 5; *Payne* Doc. 121-1 at 4.)

Dr. Lehmann stated that he could not remember how he distinguished between his legal and general consulting work, observing that "this is nine years ago" and "[t]he specifics of what happened are long lost." (*Tillman* Doc. 57-1 at 4; *Payne* Doc. 121-1 at 3.) Nevertheless, Dr. Lehmann testified that there was no overlap between his legal and non-legal work. His legal consulting task "was specifically spelled out in the contract, and so that, you know, laid out exactly what I was doing, which was distinct from the general consulting." (*Tillman* Doc. 57-1 at 5; *Payne* Doc. 121-1 at 4.) Finally, when asked whether some of his legal work was "also some of the same work and analysis you were doing just as part of the day-to-day operation at Bard," Dr. Lehmann replied:

> Not really. I was advising the company in terms of their product performance and some of the risks that were inherent in these sorts of devices. But the legal consulting, to the extent—I don't really know how much I can talk about it, but the legal consulting was a specific in-depth, comprehensive look at various aspects of the device. So it certainly covered the same device . . . .

(*Tillman* Doc. 57-1 at 5–6; *Payne* Doc. 121-1 at 4–5.) Review of the November 2004 Contract reveals that it covers Dr. Lehmann's preparation of the Report.

II. Standard

A. General

"The Federal Rules of Civil Procedure 'strongly favor full discovery whenever possible.'" *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, Case No. 6:09-cv-1002-Orl-31TBS, 2012 WL 5415108, at *2 (M.D. Fla. Nov. 6, 2012) (quoting *Farnsworth v. Proctor & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985)). Parties may ordinarily obtain discovery of "any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1).

The burden of establishing that the work product doctrine or attorney-client privilege protects potential discovery lies with the party asserting the protection. *CSX Transp., Inc. v. Admiral Ins. Co.*, Case No. 93-132-CIV-J-10, 1995 WL 855421, at *1 (M.D. Fla. July 20, 1995). "This burden can be met only by an evidentiary showing based on competent evidence, and cannot be discharged by mere conclusory or ipse dixit assertions." *Id.* (internal citations omitted).

B. Work Product Protection

The United States Supreme Court first announced that an attorney's work product made in anticipation of litigation should be protected from discovery in *Hickman v. Taylor*, 329 U.S. 495 (1947). The Court observed that "[w]ere such materials open to opposing

counsel on mere demand, much of what is now put down in writing would remain unwritten." *Id.* at 511. Accordingly, "[i]nefficiency, unfairness and sharp practices would inevitably develop in the giving of legal advice and in the preparation of cases for trial." *Id.* "The effect on the legal profession would be demoralizing." *Id.* "And the interests of the clients and the cause of justice would be poorly served." *Id.*

This rule, subsequently refined, was codified in the 1970 amendments to the Federal Rules of Civil Procedure. Wright & Miller, 8 Fed. Prac. & Proc. § 2023 (3d ed. 2010). Rule 26(b)(3)(A) now reads in relevant part:

> Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent).

In deciding whether this protection applies, a crucial question therefore is whether a document is "prepared in anticipation of litigation" within the meaning of this rule. The former Fifth Circuit, in a case binding on this Court,[12] has said:

> It is admittedly difficult to reduce to a neat general formula the relationship between preparation of a document and possible litigation necessary to trigger the protection of the work product doctrine. We conclude that litigation need not necessarily be imminent, as some courts have suggested, as long as *the primary motivating purpose* behind the creation of the document was to aid in possible litigation.

United States v. Davis, 636 F.2d 1028, 1040 (5th Cir. 1981) (emphasis added) (citations omitted). As such, the work product protections of Rule 26(b)(3) "typically apply only to

[12] The Eleventh Circuit has adopted, as binding precedent, the decisions of the United States Court of Appeals for the Fifth Circuit handed down prior to the close of business on September 30, 1981. *Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981).

documents prepared principally or exclusively to assist in anticipated or ongoing litigation." *AARP v. Kramer Lead Mktg. Grp.*, Case No. 3:03-cv-1033-J-99MCR, 2005 WL 1785199, at *2 (M.D. Fla. July 26, 2005) (internal citations omitted).

In some cases, a document may appear to serve both a business and a litigation purpose. "[I]f a party prepares a document in the ordinary course of business, it will not be protected even if the party is aware that the document may also be useful in the event of litigation." *Bridgewater v. Carnival Corp.*, 286 F.R.D. 636, 641 (S.D. Fla. 2011). To establish the applicability of the work product doctrine to such documents, it is not sufficient for a party to show only that an attorney or the attorney's agent generated the document. Corporate in-house counsel are "often called upon to perform tasks that go beyond the traditional tasks performed by lawyers." *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB, 2008 WL 1995058, at *2 (M.D. Fla. May 7, 2008) (internal quotation omitted). "If the attorney was performing other [non-legal] tasks, then the communications receive no protection from discovery." *Id.* Were the rule otherwise, businesses "may try to immunize internal [business] communications from discovery by placing legal counsel in strategic corporate positions and funneling documents through counsel." *Id.*, at *4 (treatise citation omitted). Accordingly, "each document must be perused to see whether the attorney was involved in rendering legal advice or if the document contains work product information." *Id.*, at *2.

In making this inquiry, a court need not simply accept the parties' declarations. *See Bridgewater*, 286 F.R.D. at 641 (rejecting a claim to work product protection that "rests solely on the declaration of [the general manager of the corporate party resisting discovery]"). Rather, a court applies "common sense and logic" in light of the evidence in

the record. *See id.* Additionally, a court may scrutinize the content of the subject documents for analysis that "hints at a focus on litigation." *See id.* at 642.

Finally, the Court notes that the Eleventh Circuit's "primary purpose" standard in some cases may be less protective of potential work product than the standard employed by other circuits, including the Sixth Circuit in which *Carr v. C.R. Bard, Inc.* was decided. "Other appellate courts have adopted a potentially broader 'because of' standard, which asks whether a document was prepared or obtained because of the prospect of litigation." *Adams v. City of Montgomery*, 282 F.R.D. 627, 634 (M.D. Ala. 2012). In these jurisdictions it error for the court to rest its work product determination "on a requirement that the primary or sole purpose of the [subject document] be in preparation of litigation." *United States v. Roxworthy*, 457 F.3d 590, 599 (6th Cir. 2006); *see also Carr v. C.R. Bard*, 2014 WL 463447, at *4 (citing *Roxworthy* for this proposition). Under the "because of" standard, "a document will not be protected if it would have been prepared in substantially the same manner irrespective of the anticipated litigation." *Roxworthy*, 457 F.3d at 593. The test asks the court to consider, "(1) whether a document was created because of a party's subjective anticipation of litigation, as contrasted with an ordinary business purpose, and (2) whether that subjective anticipation of litigation was objectively reasonable." *Id.*

C. Attorney-Client Privilege

State law governs privilege in federal diversity cases. *Miller v. Transamerican Press, Inc.*, 621 F.2d 721, 724 (5th Cir. 1980); *U.S. Fidelity & Guar. Co. v. Liberty Surplus Ins. Corp.*, 630 F. Supp. 2d 1332, 1335 (M.D. Fla. 2007); *see also* Fed. R. Evid. 501. Under Florida law, "[t]he attorney-client privilege applies to confidential communications made in the rendition of legal services to the client." *Southern Bell Tel. & Tel. Co. v.*

Deason, 632 So. 2d 1377, 1380 (Fla. 1994); Fla. Stat. § 90.502.[13] As with the work product doctrine, "[t]he burden of establishing the attorney-client privilege rests on the party claiming it." *Deason*, So. 2d at 1383. The Florida Supreme Court has held that in deciding whether the attorney-client privilege covers a communication between a corporation's lawyer (or the lawyer's agent) and a corporate employee, a court should consider whether:

> (1) the communication would not have been made but for the contemplation of legal services;
>
> (2) the employee making the communication did so at the direction of his or her corporate superior;
>
> (3) the superior made the request of the employee as part of the corporation's effort to secure legal advice or services;
>
> (4) the content of the communication relates to the legal services being rendered, and the subject matter of the communication is within the scope of the employee's duties;
>
> (5) the communication is not disseminated beyond those persons who, because of the corporate structure, need to know its contents.

Id. "[T]he privilege 'protects only those disclosures necessary to obtain informed legal advice.'" *Genovese v. Provident Life Ins. & Accident Ins. Co.*, 74 So. 3d 1064, 1067 (Fla. 2011) (quoting *Fisher v. United States*, 425 U.S. 391, 403 (1976)). Further, "'[i]f a communication with a lawyer is not made with him in his professional capacity as a lawyer, no privilege attaches.'" *Id.* (quoting *State v. Branham*, 952 So. 2d 618, 621 (Fla. Dist. Ct. App. 2007)).

[13] The parties agree that Florida law applies. (*See Tillman* Doc. 29 at 9 n.5; *Payne* Doc. 68 at 10 n.3)

III. Analysis

For the reasons that follow, Defendants have not carried their burden to prove that the Lehmann Report is either work product or protected by the attorney-client privilege.

A. The Lehmann Report is not protected work product.

First, the Court has scrutinized the Report itself. It does contain the words "attorney work product" and "privileged and confidential" across the top of each page. (*Tillman* Doc. 33-1 at 4–37; *Payne* Doc. 84-1 at 3–24.) However, nothing else in the Report hints at a litigation purpose. It makes no reference to any ongoing or anticipated claim or suit and contains no analysis of any particular set of facts. Rather, it relays the results of a study of incident reports contained in an FDA database and testing designed to gauge the performance of the Recovery Filter relative to its competitor devices. (*See Tillman* Doc. 33-1 at 4–37; *Payne* Doc. 84-1 at 3–24.)

Defendants' Motions rely primarily upon the Passero Affidavit , the November 2004 Contract, and excerpts from Dr. Lehmann's deposition, rather than on the contents of the Report itself. The Court will consider each item in turn and then address other record evidence.

Although the Passero Affidavit supports Defendants' claim that the Lehmann Report is protected work product, it does so in a conclusory, vague, and unconvincing manner, generally employing labels rather than specific facts. As observed above, the Passero Affidavit states that Passero hired Dr. Lehmann to prepare a report to assist the law department in advising Defendants in connection with pending litigation. (*Tillman* Doc. 29-3 at 2–3; *Payne* Doc. 68-1 at 2–3.) The affidavit states that Passero informed Dr. Lehmann of this litigation purpose and that access to the Lehmann Report was tightly restricted. (*Tillman* Doc. 29-3 at 3; *Payne* Doc. 68-1 at 3.) The affidavit does not,

however, describe how the report was used or intended to be used to aid Defendants in preparing for trial or anticipated litigation. Moreover, the affidavit fails to identify any specific case, claim, or incident, or the timing thereof.

In addition, the Passero Affidavit is not as unequivocal in declaring the Lehmann Report's litigation purpose as Defendants maintain. For example, the affidavit states that Defendants' employees were told that distribution of the Lehmann Report should be "limited to only those employees or consultants who need the report to perform their proper job functions." (*Tillman* Doc. 29-3 at 3; *Payne* Doc. 68-1 at 3.) However, the affidavit never identifies those job functions, which may or may not be related to litigation. In fact, as discussed further, *infra*, a number of employees who had no connection to litigation received and used the Report. Moreover, the affidavit is further weakened when viewed in light of the Lehmann Report itself and other relevant documents, as discussed below.

The November 2004 Contract is similarly conclusory and unpersuasive.[14] Although it does show that the Report was prepared pursuant to this separate contract, it adds little to the Report itself. For example, like the Report, it contains no reference to any particular claim, anticipated or otherwise, or any particular set of facts that caused Defendants concern over potential litigation. Although the November 2004 Contract does

[14] Since the November 2004 Contract does not change the Court's analysis, the Court need not address Plaintiffs' argument that they have been denied due process by the Court's *ex parte* consideration of this contract (*see Tillman* Doc. 79 at 3; *Payne* Doc. 142 at 3).

affix the conclusory label "[i]n anticipation of litigation" in connection with the services to be provided, the Court finds nothing else in the contract to support this label.[15]

Dr. Lehmann's deposition testimony also does not persuasively support Defendants' Motions. Dr. Lehmann testified that he had two contracts in place with Defendants in the fall of 2004, one covering general consulting work and the other covering litigation consulting. Dr. Lehmann testified that his legal assignment was "very specific." (*Tillman* Doc. 57-1 at 4; *Payne* Doc. 121-1 at 3.) His general consulting work involved "advising the company in terms of their product performance and some of the risks that were inherent in these sorts of devices." His legal consulting "was a specific in-depth, comprehensive look at various aspects of the device." (*Tillman* Doc. 57-1 at 5–6; *Payne* Doc. 121-1 at 4–5.)

However, the Lehmann Report itself appears to fit within "advising the company in terms of their product performance and some of the risks that were inherent in these sorts of devices," as much as an "in-depth look at various aspects" of the device. Although the Report clearly falls within the tasks described in the November 2004 Contract, Dr. Lehmann's testimony suggests that the line between his general consulting work and his "litigation" work was not that sharp. Moreover, Dr. Lehmann does not explain how his services related to any litigation preparation. And he does not identify a specific matter or event, potential or otherwise, on which he was a consultant. (*Tillman* Doc. 57-1 at 3; *Payne* Doc. 121-1 at 2.)

[15] The Court has not discussed the contents of the contract in detail since the Court allowed Defendants to submit it *ex parte* and *in camera*. Also, a detailed discussion is unnecessary.

As argued by Plaintiffs, documents prepared at or around the time of the Lehmann Report more convincingly show a primary broader business purpose for the Report. For example, Plaintiffs attach to their Responses a document entitled Recovery Filter Migration Remedial Action Plan, dated January 4, 2005 ("the Plan" or "RAP"). (*Tillman* Doc. 33-2; *Payne* Doc. 84-2.) The Plan incorporates and makes liberal use of the Lehmann Report, even attaching it in full as an exhibit. The Table of Contents of the Plan lists the Plan itself, the Lehmann Report, and a Health Hazard Evaluation ("HHE"), prepared on December 17, 2004 by Dr. David Ciavarella, Defendants' then-Medical Director. (*Tillman* Doc. 33-2 at 3; *Payne* Doc. 84-2 at 3.)

The regulations governing medical device manufacturers such as Defendants require Defendants to "establish and maintain procedures for implementing corrective and preventative action." 21 C.F.R. § 820.100(a). Brian Barry, a member of the Corporate Product Assessment team that reviewed the Plan, testified at deposition that the Plan was required by regulation. (*Tillman* Docs. 65-1 at 3, 79 at 3; *Payne* Doc. 142 at 3.) *See also Carr v. C.R. Bard, Inc.*, 2014 WL 463447, at *1 (N.D. Ohio Feb. 5, 2014) (observing that defendants, pursuant to regulation, "established procedures for monitoring device failures, including the preparation of a 'Remedial Action Plan,'" and that "[e]ach RAP includes, in turn, a Health Hazard Evaluation").

The Plan paints a picture at odds with the claims in Defendants' motion papers and the Passero Affidavit. It states that Defendants commissioned the Lehmann Report not in anticipation of litigation, but "as part of an ongoing evaluation of [the Recovery Filter]," and that the "purpose" of the Lehmann Report was to "study the risks and benefits of the [filter], with an emphasis on its use in bariatric surgery and trauma patients."

(*Tillman* Doc. 33-2 at 6–7; *Payne* Doc. 84-2 at 6–7.) The Plan states that "[a] consultant was retained for this purpose," rather than any litigation purpose. (*Tillman* Doc. 33-2 at 7; *Payne* Doc. 84-2 at 7.) The Plan then cites the Lehmann Report extensively. (*Tillman* Doc. 33-2 at 7–8; *Payne* Doc. 84-2 at 7–8.)

The Plan also indicates that "[t]he Division Product Assessment Team," who generated the Plan, was assigned to review the "consultant's document," i.e., the Lehmann Report. This assignment was given on December 9, 2004, approximately one week *before* Dr. Lehmann submitted the final report to Ms. Passero on December 15, 2004. (*Tillman* Doc. 33-2 at 8, 14; *Payne* Doc. 84-2 at 8, 14.) This team included BPV's Vice President of Quality Assurance, Vice President of Research and Clinical Affairs, Vice President of Research and Development, the Director of Research and Development for Interventional Products, and the Inferior Vena Cava Filter Marketing Manager. This team included no members of Defendants' law department. (*Tillman* Doc. 33-2 at 8; *Payne* Doc. 84-2 at 8.) The team stated that through its review it "endeavors to identify the actions required to help mitigate the adverse events associated with the [Recovery Filter]." (*Tillman* Doc. 33-2 at 9; *Payne* Doc. 84-2 at 9.)

The Plan itself contains no legal analysis and makes no mention of ongoing or anticipated litigation. Rather, the Plan is designed to satisfy regulatory requirements and to assist corporate officers in deciding how to respond to potential issues with the Recovery Filter. The Plan contains a recommended course of action (*Tillman* Doc. 33-2 at 11, 13; *Payne* Doc. 84-2 at 11, 13) and was submitted to the "Corporate Product Assessment Team," who reviewed and approved it on December 28, 2004 (*Tillman* Doc. 33-2 at 4; *Payne* Doc. 84-2 at 4). The Plan recommended further surveys to gain

additional information, discussion of whether "additional warnings or precautions are appropriate, or if further action is required," and evaluation of the information "for discussion with the FDA once a final plan of action has been agreed upon" by the Division and Corporate Product Assessment Teams. (*Tillman* Doc. 33-2 at 13; *Payne* Doc. 84-2 at 13.)

Plaintiffs also point to deposition testimony that contradicts the Passero Affidavit. Dr. Ciavarella, who prepared the HHE attached to the Plan and who was a member of the Corporate Product Assessment Team, testified that nobody ever told him that Dr. Lehmann prepared the Report in anticipation of litigation or that it was intended to be protected work product.[16] (*Tillman* Docs. 32-9 at 11–12, 46-2 at 15–16; *Payne* Doc. 79-2 at 8–9.) Although Defendants observe that Dr. Ciavarella also testified that he believed CRB's law department retained Dr. Lehmann and he understood that the Lehmann Report was confidential, he still gave no indication that the Report was used for anything but a business purpose. (*Tillman* Doc. 36-2 at 3–5; *Payne* Doc. 94-1 at 3–5.)

The HHE, which also refers extensively to the Lehmann Report, itself suggests that the Report served a business, rather than litigation, purpose. Dr. Ciavarella testified that he used the Report in preparing the HHE "to fulfill [CRB's] regulatory obligations," not for a litigation purpose, and that he cited various parts of the Report in this evaluation. (*Tillman* Doc. 32-9 at 11–12; *Payne* Doc. 79-2 at 8–9.) The HHE is dated December 17, 2004, only two days after the date of the Report. It states:

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[16] Tillman also relies on excerpts from the deposition of Brian Hudson, "a Bard engineer" (*see Tillman* Docs. 46 at 2, 46-2 at 7–8). Hudson also testified that he used the Lehmann Report in performing his job and no one ever told him it had a litigation purpose. (*See Tillman* Doc. 46-2 at 16.)

> Based on awareness of reports of patient death associated with migration of the Recovery inferior vena cava (IVC) filter, Bard requested an independent study of the risks and benefits of the Recovery filter, with an emphasis on its use in bariatric surgery and trauma patients. A consultant [Dr. Lehmann] was retained for this purpose.

(*Tillman* Doc. 33-2 at 50; *Payne* Doc. 84-2 at 49.)

In light of the foregoing, the Court cannot conclude that Defendants have met their burden to prove that the Report was created for the primary purpose of aiding Defendants in anticipated or ongoing litigation. Indeed, Defendants' Motions go a step further and state that the document was drafted "entirely because of anticipated and ongoing litigation." (*Tillman* Doc. 29 at 5; *Payne* Doc. 29 at 6.) However the relevant documents and depositions show that a business purpose was at least equivalent, and indeed primary, to any litigation purpose. The conclusory labels in the November 2004 Contract and the Passero Affidavit do not change this analysis.

B. The Lehmann Report is not a privileged attorney-client communication.

As discussed in detail above, the Court finds that Defendants have not met their burden to prove that they commissioned the Lehmann Report primarily in anticipation of litigation. Rather, the Court concludes that the Lehmann Report served primarily general business and regulatory compliance functions. The fact that Defendants used their legal department to serve as an intermediary between Dr. Lehmann and their other employees does not alter this conclusion. Consequently, Defendants have failed to establish that the communications between Dr. Lehmann and Defendants' lawyers and employees, memorialized in the Report, "would not have been made but for the contemplation of legal services," that the Report "relates to the legal services being rendered," or that the Report was not "disseminated beyond those persons who, because of the corporate structure,

need to know its contents." *See Southern Bell Tel. & Tel. Co. v. Deason*, 632 So. 2d 1377, 1383 (Fla. 1994). Defendants' claim to attorney-client privilege therefore also fails.

C. *Carr* and *Phillips*

The Court has carefully considered the non-controlling precedent addressing the Lehmann Report, particularly *Carr* and *Phillips*, both of which are thorough and well-reasoned. Regarding *Carr*, as previously noted, it was decided under the Sixth Circuit's "because of," rather than the Eleventh Circuit's "primary purpose," test. Moreover, in *Carr* the court stated: "[Plaintiff's] discussion of the link between the Lehmann Report and the subsequently produced RAP and HHE faces a chronological problem." 2014 WL 463447, at *4. However, this Court concludes, based on the record before it, that the chronology of events is indicative of a business purpose. Although the Lehmann Report predates the HHE, it does so by only two days. Moreover, the Division Product Assessment Team, who created the RAP, was assigned to review the Lehmann Report before the Report was even finalized. This record therefore indicates that, before completion of the Report, Defendants had already planned to use it for business and regulatory compliance purposes. In the Court's view, that is a strong indication of the overriding purpose of the Report. In contrast, there are only conclusory, factually unsupported assertions of a litigation purpose in this case.

Regarding *Phillips*, which addressed fifty separate discovery items in dispute, it too was decided, at least on reconsideration, under the "because of" standard, which recognizes that "dual purpose" documents are generally protected. 290 F.R.D. at 670. Moreover, apparently the record in *Phillips* was more convincing than the record at bar that Defendants "had received multiple product liability claims" by November 2004. *Id.* at 671. Although Defendants' Motions make similar assertions (*Tillman* Doc. 29 at 2; *Payne*

Doc. 68 at 2) there is no evidence of that in this record, and no evidence connecting the Lehmann Report to any such claims. Thus, although the Court has fully considered this authority, it adheres to the analysis contained herein.

Accordingly, it is **ORDERED**:

Defendants' Motions for Protective Order (***Tillman* Doc. 29; *Payne* Doc. 68**) are **DENIED**.

DONE AND ORDERED at Jacksonville, Florida, on March 28, 2014.

Joel B. Toomey

JOEL B. TOOMEY
United States Magistrate Judge

Copies to:

Counsel of Record

EXHIBIT 17

To Plaintiffs' Response to Bard's Motion for Protective Order

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

LESSIE TILLMAN,

Plaintiff,

vs. Case No. 3:13-cv-222-J-34JBT

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

_____/

ORDER

THIS CAUSE is before the Court on Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Objection to, and Motion to Set Aside, Magistrate's Order Denying Defendants' Motion for Protective Order (Doc. 83; Objections) filed on April 11, 2014. Pursuant to Rule 72, Federal Rules of Civil Procedure (Rule(s)), and 28 U.S.C. § 636, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.[1] object to the Order (Doc. 81; Order) entered by the Honorable Joel B. Toomey, United States Magistrate Judge, on March 28, 2014. In the Order, Magistrate Judge Toomey denied Defendants' Motion for Protective Order (Doc. 29; Motion for Protective Order). See Order at 23. Bard contends that the Magistrate Judge's Order is contrary to law and requests that this Court reverse the Order. See Objections at 1. Plaintiff Lessie Tillman (Tillman) responded to the Objections on June 13, 2014. See Plaintiff's Response to Defendants' Objection to, and Motion to Set Aside,

[1] The Court will refer to the Defendants collectively in the singular as "Bard."

Magistrate's Order Denying Defendants' Motion for Protective Order (Doc. 89; Response to Objections). In support of its Objections, Bard also filed several notices of supplemental authority. See Defendants' C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Notice of Supplemental Authority in Support of Objection to, and Motion to Set Aside, Magistrate's Order Denying Defendants' Motion for Protective Order (Docs. 86, 87, 115, 140).

I. Standard of Review

Inasmuch as the Magistrate Judge's March 28, 2014 Order on Defendants' Motion for Protective Order does not dispose of a claim or defense of any party, it is a nondispositive order. See Smith v. Sch. Bd. of Orange Cnty., 487 F.3d 1361, 1365 (11th Cir. 2007) (per curiam). As such, to prevail in its Objections, Bard must establish that the conclusions to which it objects in the Order are clearly erroneous or contrary to law. See Rule 72(a); 28 U.S.C. § 636(b)(1)(A); see also Merritt v. Int'l Bhd. of Boilermakers, 649 F.2d 1013, 1016-17 (5th Cir. Unit A June 1981);[2] Nat'l Ass'n for the Advancement of Colored People v. Fla. Dep't of Corrs., 122 F. Supp. 2d 1335, 1337 (M.D. Fla. 2000); Williams v. Wright, No. 3:09-cv-055, 2009 WL 4891825, at *1 (S.D. Ga. Dec.16, 2009) ("A district court reviewing a magistrate judge's decision on a nondispositive issue 'must consider . . . objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.'") (quoting Rule 72(a)).[3] "Clear error is a highly deferential standard of review." Holton v. City of Thomasville

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[2] In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) the Eleventh Circuit adopted as binding precedent all the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

[3] "Although an unpublished opinion is not binding . . ., it is persuasive authority." United States v. Futrell, 209 F.3d 1286, 1289 (11th Cir. 2000) (per curiam); see generally Fed. R. App. P. 32.1; 11th Cir. R. 36-2 ("Unpublished opinions are not considered binding precedent, but they may be cited as persuasive authority.").

Sch. Dist., 425 F.3d 1325, 1350 (11th Cir. 2005) (citation omitted). "[A] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Id. (citations and quotations omitted); see also Weeks v. Samsung Heavy Indus. Co., Ltd., 126 F.3d 926, 943 (7th Cir. 1997) ("The clear error standard [under Rule 72(a) and 28 U.S.C. § 636(b)(1)(A)] means that the district court can overturn the magistrate judge's ruling only if the district court is left with the definite and firm conviction that a mistake has been made."). A magistrate judge's order "is contrary to law 'when it fails to apply or misapplies relevant statutes, case law, or rules of procedure.'" Botta v. Barnhart, 475 F. Supp. 2d 174, 185 (E.D.N.Y. 2007) (quoting Catskill Dev., L.L.C. v. Park Place Entm't Corp., 206 F.R.D. 78, 86 (S.D.N.Y. 2002); see also Pigott v. Sanibel Dev., LLC, Civil Action No. 07-0083-WS-C, 2008 WL 2937804, at *5 (S.D. Ala. July 23, 2008) (similar) (citation omitted); Schaaf v. SmithKline Beecham Corp., Civil Action No. 1:04-cv-2346-GET, 2008 WL 489010, at *3 (N.D. Ga. Feb. 20, 2008) (similar) (citation omitted).[4] Moreover, a magistrate judge is afforded broad

[4] The Court notes some authority that the "contrary to law" standard invites plenary review of a magistrate judge's legal conclusions. See e.g., Haines v. Liggett Grp., Inc., 975 F.2d 81, 91 (3d Cir. 1992); Milwaukee Carpenter's Dist. Council Health Fund v. Philip Morris, Inc., 70 F. Supp. 2d 888, 892 (E.D. Wis. 1999); Computer Econ., Inc. v. Gartner Grp., Inc., 50 F. Supp. 2d 980, 983 & n.2 (S.D. Cal. 1999). In this Circuit, however, the "contrary to law" standard has been distinguished as more deferential than de novo review. See Merritt, 649 F.2d at 1016-17 ("[A] magistrate['s nondispositive orders] are reviewable under the 'clearly erroneous and contrary to law' standard; they are not subject to a de novo determination as are a magistrate's proposed findings and recommendations."). Nonetheless, even to the extent the "contrary to law" standard may invite some level of plenary review, it is evident that because a magistrate is afforded broad discretion as to discovery matters, reversal as to a magistrate's discovery-related order is appropriate only where that discretion is abused. See generally Johnson v. Bd. of Regents of the Univ. of Ga., 263 F.3d 1234, 1269 (11th Cir. 2001) ("[W]e accord district courts broad discretion over the management of pretrial activities, including discovery and scheduling."); Botta, 475 F. Supp. 2d at 185; Doe v. Hartford Life & Accident Ins. Co., 237 F.R.D. 545, 547-48 (D.N.J. 2006); Doe v. Marsh, 899 F. Supp. 933, 934 (N.D.N.Y. 1995); see also CHARLES ALAN WRIGHT, ARTHUR R. MILLER & RICHARD L. MARCUS, FEDERAL PRACTICE AND PROCEDURE § 3069 (2d ed. 1997) ("Regarding legal issues, the language 'contrary to law' appears to invite plenary review. But many matters such as discovery scheduling or disputes might better be characterized as suitable for an abuse-of-discretion analysis.").

discretion in issuing nondispositive pretrial orders related to discovery such as the March 28, 2014 Order. See Tracy P. v. Sarasota Cnty., No. 8:05-CV-927-T-26EAJ, 2007 WL 1364381, at *2 (M.D. Fla. May 9, 2007); see also Rule 6.01(c)(18), Local Rules, United States District Court, Middle District of Florida (Local Rule(s)) (authorizing magistrate judges to supervise and determine pretrial proceedings and motions in civil cases, including discovery motions).

II. Background & Summary of the Arguments

Bard's Motion for Protective Order concerns a report prepared for Bard by Dr. John Lehmann in which he sets out the results of his investigation into Bard's inferior vena cava (IVC) filters. See Motion for Protective Order at 1-2; Plaintiff's Opposition to Defendants' Motion for Protective Order and Brief in Support Thereof (Doc. 33; Response to Motion), Ex. 1 (Lehmann Report). In the Motion for Protective Order, Bard maintained that the Lehmann Report is protected by the attorney-client privilege and work-product doctrine. See Motion for Protective Order at 1. As such, Bard asked the Court to order Tillman to destroy any copies of the Lehmann Report in her possession and to prohibit Tillman from using the Lehmann Report in prosecuting this case. See id. at 10-11. The Magistrate Judge determined that the Lehmann Report was not protected by either of these doctrines, and denied the Motion for Protective Order. See Order at 21-23. Because the Magistrate Judge's Order sets forth in detail the background of this litigation, the facts underlying Bard's Motion for Protective Order, and the relevant evidence, the Court will not further summarize the factual background here.

In its Objections, Bard contends that the Magistrate Judge applied an incorrect legal standard in determining that the Lehmann Report was not protected by the work-product

doctrine.[5] See Objections at 5. Specifically, the Magistrate Judge determined that to be entitled to work-product protection, "'the primary motivating purpose behind the creation of the document'" must be to aid in possible litigation. See Order at 11 (quoting United States v. Davis, 636 F.2d 1028, 1040 (5th Cir. Unit A Feb. 1981)). According to Bard, the "primary purpose" test set forth in Davis is mere dicta, and therefore, not binding on this Court. See Objections at 6. Moreover, Bard maintains that prior binding precedent precludes the application of this standard. Id. at 9-10 (citing Hoover v. U.S. Dep't of the Interior, 611 F.2d 1132, 1139 n.8 (5th Cir. 1980)). Bard asserts that the Magistrate Judge should have applied the "because of" formulation of the work product analysis adopted by a majority of other circuits, not the "primary purpose" test. Id. at 11-12. Under the "because of" standard, a document is protected as work-product where it "'can fairly be said to have been prepared or obtained because of the prospect of litigation.'" See id. at 5 (quoting Milinazzo v. State Farm Ins. Co., 247 F.R.D. 691, 698 (S.D. Fla. 2007)). Bard argues that "[h]ad the Magistrate [Judge] applied the 'because of' standard," he would have found that the Lehmann Report was protected work-product. See id. at 14. In support, Bard cites to decisions in which other courts have found the Lehmann Report to be protected work-product applying the "because of" standard. See Carr v. C.R. Bard, Inc., 297 F.R.D. 328, 331-33 (N.D. Ohio 2014); Phillips v. C.R. Bard, Inc., 290 F.R.D. 615, 635-36, 670-71 (D. Nev. 2013); Defendants' Reply to Plaintiff's Objection and Response to Defendants' Filing of Supplemental Authority Regarding Motion for Protective Order (Doc. 68), Ex. 1 (collecting decisions of Arizona state

[5] Bard does not object to the Magistrate Judge's conclusion that the Lehmann Report is not protected by the attorney-client privilege, and thus, the Court will not address that portion of the Order.

courts finding the Lehmann Report to be protected work-product); Ebert v. C.R. Bard, Inc., No. 12-01253 (E.D. Penn. Apr. 24, 2014) (Doc. 86-1); Cason v. C.R. Bard, Inc., No. 1:12-CV-1288-MHS (N.D. Ga. May 12, 2014) (Doc. 87-1); see also Alexander v. C.R. Bard, Inc., No. 3:12-CV-5187-O-BK (N.D. Tex. Aug. 20, 2014) (Doc. 115) (finding the Lehmann Report to constitute protected work-product under the "primary purpose" standard); Jones v. C.R. Bard, Inc., No. 3:13-CV-599-K (BF) (N.D. Tex. Sept. 15, 2015) (Doc. 140-1) (same). As such, Bard contends that the Court should find that the Magistrate Judge's Order is contrary to law and set it aside.

In her Response, Tillman maintains that the "because of" standard still requires an inquiry into "the when, why, and for what primary purpose a document was created." See Response to Objections at 5. As such, Tillman contends that the substance of the Magistrate Judge's analysis encompasses both the "primary purpose" and the "because of" standards and finds that Bard has failed to demonstrate that the Report is protected work-product under either standard. Id. Based on the Magistrate Judge's factual findings, Tillman argues that Bard has failed to meet its burden to justify the protection of the Lehmann Report, and has "failed to demonstrate that Magistrate Judge Toomey's ruling is contrary to law . . . ." Id. at 8.

III. Discussion

Upon review, the Court observes that some district courts within the Eleventh Circuit have moved away from applying the "primary purpose" test based on an interpretation of Davis as dicta, and identification of Hoover as potentially contradictory prior precedent. See Regions Fin. Corp. v. United States, No. 2:06-CV-00895-RDP, 2008 WL 2139008, at

*3-4 (N.D. Ala. May 8, 2008) (citing United States v. Adlman, 134 F.3d 1194, 1198-1203 (2d Cir. 1998)); United States v. Gericare Med. Supply Inc., No. CIV.A.99-0366-CB-L, 2000 WL 33156442, at *2 (S.D. Ala. Dec. 11, 2000); see also Jones v. Tauber & Balser, P.C., 503 B.R. 510, 515 n.3 (N.D. Ga. Aug. 26, 2013); Adams v. City of Montgomery, 282 F.R.D. 627, 634 (M.D. Ala. 2012). Nonetheless, the Eleventh Circuit Court of Appeals has not yet considered the issue and many courts in this district still apply the primary purpose standard. See Hancock Bank v. Hill Street, L.L.C., No. 3:13-cv-71-J-25MCR, 2013 WL 6815055, at *6 (M.D. Fla. Dec. 24, 2013); Everbank v. Fifth Third Bank, No. 3:10-cv-1175-J-12TEM, 2012 WL 1580778, at *3 (M.D. Fla. May 4, 2012); Every Penny Counts, Inc. v. Am. Express Co., No. 8:07-cv-1255-T-26MAP, 2008 WL 2074407, at *2 (M.D. Fla. 2008); U.S. Fid. & Guar. Co. v. Liberty Surplus Ins. Corp., 630 F. Supp. 2d 1332, 1337 (M.D. Fla. 2007) ("The determinative question is whether the prospect of litigation was the primary motivating purpose behind the creation of a particular document."); Lockheed Martin Corp. v. L-3 Commc'ns Corp., No. 6:05-cv-1580-Orl-31KRS, 2007 WL 2209250, at *9 (M.D. Fla. July 29, 2007); see also Bridgewater v. Carnival Corp., 286 F.R.D. 636, 641 (S.D. Fla. 2011). Notably, some authorities appear to equate or blend the two standards as Tillman does. See Montgomery Cnty. v. MicroVote Corp., 175 F.3d 296, 305-06 (3d Cir. 1999) (Greenberg, C.J., concurring); United States v. Rockwell Int'l, 897 F.2d 1255, 1266 (3d Cir. 1990); see also Adams, 282 F.R.D. at 634; Spirit Master Funding, LLC v. Pike Nurseries Acquisition, LLC, 287 F.R.D. 680, 685 (N.D. Ga. 2012).

Thus, while some courts have criticized the "primary purpose" test, upon review of the case law cited in the Magistrate Judge's Order, and in light of the split of authority, the Court

does not find that the Order is "contrary to law." See Ruskin Co. v. Greenheck Fan Corp., No. 08-CV-60902, 2009 WL 383349, at *2 (S.D. Fla. Feb. 12, 2009); Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Donaldson Co., Inc., No. 10–4948 (JRT/JJG), 2014 WL 2865900, at *5 (D. Minn. June 24, 2014). Significantly, the Court is not convinced that the decision in Hoover precludes the application of the primary purpose test under these circumstances.[6] The Hoover court briefly considered, in a single footnote, whether an appraisal report concerning property the government sought to acquire was prepared "in anticipation of litigation." Id. at 1139 n.8. The court noted that "[i]t is clear that the appraisal report was prepared in anticipation of litigation," because "the government must necessarily anticipate that negotiations for purchase will fail, thereby requiring condemnation." Id. The court then stated that "[a]ppraisals are therefore obtained both for the purpose of providing a basis for an offer, and to support a claim of just compensation at a subsequent condemnation suit." Id. As such, it appears that the Hoover court viewed the litigation purpose of the appraisal to be at least intertwined with and inseparable from the business purpose of the document. The decision contains no analysis of the appropriate test for determining whether a document is created "in anticipation of litigation" where the prospect of litigation is not imminent, or where a business purpose is a separate and primary reason for the document's creation. Thus, because the Hoover court does not indicate which purpose it viewed as the

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[6] Notably, although Tillman referenced the "primary purpose" standard in her Response, see Response to Motion at 15, Bard did not argue in its reply before the Magistrate Judge that the "primary purpose" test is precluded by prior binding precedent. See generally Defendants' Reply in Support of Motion for Protective Order (Doc. 36).

"primary" reason for the creation of the appraisal report, this Court will not interpret the decision in such a way as to conflict with the standard set forth in Davis.[6]

Moreover, even under the "because of" standard, the Magistrate Judge's decision that the Lehmann Report is not protected work-product is not clearly erroneous or contrary to law. In Adlman, the Second Circuit describes the "because of" standard as warranting protection where "'in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation.'" See Adlman, 134 F.3d at 1202 (quoting Charles Alan Wright, Arthur R. Miller, and Richard L. Marcus, 8 Federal Practice & Procedure § 2024, at 343 (1994)).[7] However, under this formulation "documents that are prepared in the ordinary course of business or that would have been created in essentially similar form irrespective of the litigation" are still not protected. Id. Indeed, "[e]ven if such documents might also help in preparation for litigation, they do not qualify for protection because it could not fairly be said that they were created 'because of' actual or impending litigation." Id. As such, a court must determine what purpose was the "'driving force'" behind the creation of the document. See United States v. Roxworthy, 457 F.3d 590, 595 (6th Cir. 2006) (quoting Nat'l Union Fire Ins. Co. of Pittsburg, Pa. v. Murray Sheet Metal Co., Inc., 967 F.2d 980, 984 (4th Cir. 1992)).

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[6] The Court is further persuaded that the Hoover decision does not preclude the application of the "primary purpose" standard given that the Fifth Circuit itself continues to apply the primary purpose standard. See United States v. El Paso Co., 682 F.2d 530, 542 (5th Cir. 1982).

[7] Notably, the very treatise from which the Second Circuit derives the "because of" standard goes on to explain that "[t]he focus is on whether specific materials were prepared in the ordinary course of business, or were principally prompted by the prospect of litigation." See Wright, Miller, & Marcus, supra, § 2024 (emphasis added). It is in this regard, the treatise writers explain, that a "dual purpose" document may be protected "even though a nonlitigation purpose can be ascertained." Id.

Here, the Magistrate Judge thoroughly considered the "nature of the document and the factual situation" based on the evidence presented.[8] See Order at 15-21. The Magistrate Judge found that the content of the Lehmann Report itself did not "hint[ ] at a litigation purpose," and that the affidavit of Bard's Assistant General Counsel, Donna Passero, supports work product protection only in a "conclusory, vague, and unconvincing manner, generally employing labels rather than specific facts." Id. at 15; see also Motion for Protective Order, Ex. 3 (Passero Affidavit). Judge Toomey observed that the Lehmann Report, Passero Affidavit, and excerpts from a deposition of Lehmann (Doc. 57-1; Lehmann Deposition) do not contain any reference to a specific case, claim, incident, or any particular set of facts that caused concern over potential litigation. See Order at 15-17. The Magistrate Judge noted that both Lehmann and Passero failed to explain how the Lehmann Report was used or intended to be used to aid Bard in preparing for trial or anticipated litigation. Id. at 16-17. In addition, Judge Toomey found the content of the Lehmann Report "contains no legal analysis and makes no mention of ongoing or anticipated litigation," rather it "is designed to satisfy regulatory requirements and to assist corporate officers in deciding how to respond to potential issues with the Recovery Filter." Id. at 19. Moreover, he discusses why "documents prepared at or around the time of the Lehmann Report more convincingly show a primary broader business purpose for the Report." Id. at 18.

The Magistrate Judge's analysis of the document and the factual circumstances surrounding its creation and his determination that the record reveals an absence of

[8] Bard does not object to the Magistrate Judge's factual findings or recitation of the evidence and the Court will not conduct a de novo review of the evidence.

persuasive evidence that a litigation purpose was the "driving force" behind the creation of the Lehmann Report is not clearly erroneous. While other courts have given greater weight to the statements of a litigation purpose in the Passero Affidavit and Lehmann Deposition, Judge Toomey was permitted to make his own assessment. His view of this evidence as vague and conclusory was not clearly erroneous. Moreover, Judge Toomey carefully considered and weighed the additional evidence regarding the preparation of the Lehmann Report, its distribution and use, and its intended purpose as of the time of its creation. Upon review of the relevant authority, as well as the factual findings set forth in the Order, this Court is not left with a "definite and firm conviction that a mistake has been committed." See Holton, 425 F.3d at 1350.[9] Because the Magistrate Judge's decision to deny the Motion for Protective Order is not clearly erroneous or contrary to law, the Court will overrule Bard's Objections. In light of the foregoing, it is

ORDERED:

[9] The Court acknowledges that several courts have reached a contrary conclusion. At least some of those decisions were based on a more developed factual record than was presented to the Magistrate Judge in this case, while others were based on a similar record. None, however, are binding on the Magistrate Judge who independently and exhaustively considered the record as a whole in reaching his determination. See Notices (Docs. 115, 140); see also Order at 22-23. The determination of the applicability of the work product doctrine to the Lehmann Report in this case is a close call. But on this record, and in light of the deferential standard of review applied to a magistrate judge's decision on a non-dispositive matter, the Court is not persuaded that the Order must be overturned.

Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Objection to, and Motion to Set Aside, Magistrate's Order Denying Defendants' Motion for Protective Order (Doc. 83) is **OVERRULED AND DENIED**.

DONE AND ORDERED in Jacksonville, Florida, this 10th day of March, 2015.

MARCIA MORALES HOWARD
United States District Judge

lc11
Copies to:

Counsel of Record

EXHIBIT 18

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 19

To Plaintiffs' Response to Bard's Motion for Protective Order

Exhibit No. 1
CHARLENE FRIEDMAN

Updated Health Hazard Evaluation

DATE: July 9, 2004 DRAFT DRAFT DRAFT

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Limb Fractures of Recovery® Filter

Summary:

Conclusion: The Severity category for the risk of thrombus-associated filter migration is Catastrophic, and the Frequency category is Remote (approximately 0.05%). The Hazard Risk Matrix Number is 8.

Description of the Problem: From January 2002 through June 2004, there have been 17 reports of limb fractures of the Recovery Filter, part of the Recovery Filter System for use in the Vena Cava. During this period, approximately 12,700 units have been sold. Assuming about 2500 units on the shelf (based on 2.5 units each for 992 accounts), about 10,200 Recovery filters have been implanted. The reported fracture rate is thus 17/10,200, a rate of 0.2% or 1 per 600 filters implanted. Fifteen fractures were noted at the time of retrieval (see below); thus, the rate of symptomatic fractures is 2/10,200, 0.02% or 1 per 5,100 filters implanted. The reported rate of serious injuries due to Recovery fracture (see below) is 1/10,200, 0.01% or 1 per 10,000 filters implanted.

In 1 of the 17 reports, the filter was "slightly angulated" upon deployment. Placement was reported as normal in 6 cases and no information about the placement of the filter is available in the remaining 10 cases. The indications for filter placement were prophylactic in 7 cases, unknown in 5 cases, and on-label in 5 cases. The fractured limbs were discovered at the time of scheduled filter retrieval in 15/17 cases (88%). None of these 15 patients had symptoms related to their fractured filter or retained filter fragments, either before or after retrieval. Two of the 17 patients (12%) presented with symptoms that prompted evaluation of the filter. One patient underwent a CT scan for a complaint of chest pain. The filter arm was noted in the R ventricle, but the patient's physicians were unable to state that the filter fragment was the cause of the chest pain. In the second symptomatic case, the patient presented with sudden shortness of breath and syncope. Hemopericardium and cardiac arrhythmia were diagnosed. A detached filter arm was noted in the ventricular wall, and it was removed during open heart surgery.

In 6 of the cases, hooks (leg ends) were detached; none of them were retrieved, i.e., they all remain in the patient, presumably bound to the wall of the inferior vena cava (IVC). A total of 20 arm fragments were reported in 14 cases (3 patients had detached hooks and arms). Eleven of 20 arms (55%) remain in the patient, and in 6 patients (30%), the detached arms migrated to the heart or lungs. Two detached arms have not been located; at least 1 of these is thought to remain *in vivo*. Information concerning the size of the retained filter fragments is available in only 4 cases; the hooks range in size from 3.6 to 4.1 mm, while the size of the only measured arm fragment was 21.6 mm. The time range for discovery of the fracture after implantation is 30 to 237 days, with a median time of 95 days.

The root cause of the fractures has not been determined, and an in vitro test method to simulate the in vivo environment does not yet exist. The arm fractures have occurred in a consistent location at the top of the filter.

The Actual Occurrence of Injuries: Serious injury has occurred in only 1 patient, the one in which open heart surgery was required to remove a filter arm that had pierced the ventricle and given rise to syncope

presumed due to an arrthymia. Another patient presented with chest pain of undetermined origin. The remaining cases have not reported symptoms or associated injury up to the time of this HHE.

Human Exposure to the Problem: As noted above, about 10,000 Recovery filters have been placed.

General Consequences: Most cases of filter fracture, both those reported here and those in the literature, are without consequence.[1,2] As seen in one case associated with the Recovery filter, migration of filter fragments to the heart or lung has the potential to cause tissue erosion and associated cardiac arrhythmias and tamponade, pulmonary hemorrhage and airway damage. Any patient with a patent foramen ovale is at additional risk of paradoxical embolization of the filter fragments, with the possibility of stroke or other end organ damage.

Population Exposed to the Risk: All patients in whom a vena cava filter is placed are at risk for this complication.

Mitigating/Predisposing Factors in the Population at Risk: Unknown. It is theoretically possible that hemodynamic stresses predisposing to fracture might result from mis-alignment of the filter in the IVC. However, the reports do not include evidence or even suspicion of mis-alignment.

Nature & Seriousness of the Risk: The effect of filter fracture is no discernible effect in most cases. Serious injury or even sudden death may occur in rare cases. In the MAUDE database, 25 cases of fractured IVC filters from manufacturers other than CR Bard are listed for the period of 2000 through 1Q2004. No deaths were reported, and serious injury was reported in 3 cases (1 case: fragment pierced the kidney; 1 case – fragments pierced the spine and aorta; 1 case – fragment lodged in the liver).

Likelihood of Occurrence of the Problem: No well-controlled trial exists to answer this question definitively for other filters. Review of the literature reveals a risk of filter migration in the range of a few percent. Kinney quotes a fracture rate of 1%,[1] while Streiff quotes rates from published studies of 0%, 1.7%, 2.8% and 14.1%, respectively, for the Greenfield, Vena Tech, Bird's nest and SNF filters.[2] Greenfield and Proctor[3], Ferris et al.,[4] and McCowan et al.[5] quote rates of fracture of 0.05%, 2%, and 10%, respectively.

The MAUDE database contains 25 reports of filter fracture from 4 manufacturers other than CR Bard in the period of 2000 through 1Q2004. Market information permits an estimate of about 425,000 IVC filters implanted from these 4 manufacturers during this time. Symptoms and serious injury were reported in 3 cases each, and death in no cases. The *MDR rates* of complications for other manufacturers filter are therefore:

Overall fracture rate:	25/425,000, 0.006% or 1 per 17,000 filters
Symptomatic rate:	3/425,000, 0.0007% or 1 per 141,667 filters
Serious injury rate:	3/425,000, 0.0007% or 1 per 141,667 filters
Death rate:	0%

These MDR reported fractures occurred in permanent filters. There have been no reports of fracture in 2 retrievable filters, the Cook Tulip and Cordis Optease, with an estimated 4,000 and 1,500 filters implanted, respectively.

Reported fracture rate data for the Recovery filter are as follows:

Overall fracture rate:	17/10,200, 0.2% or 1 per 600 filters
Symptomatic rate:	2/10,200, 0.02% or 1 per 5,100 filters
Serious injury rate:	1/10,200, 0.01% or 1 per 10,200 filters
Death rate:	0%

These MDR rates are not directly comparable to the observed rates with the Recovery filter for several reasons. First, the MAUDE database reflects only those events reported by the manufacturers, who can differ widely in their interpretation of reporting requirements. Thus different manufacturers may not classify all episodes of fracture as MDR reportable. Perhaps more importantly, however, the Recovery filter is a retrievable filter, and the fracture event was discovered prior to retrieval in 88% of cases (15/17) at a median time of 95 days after implantation. Fractures in permanent filters are discovered only incidentally, as routine monitoring of implanted filters is not common practice. This could lead to an underreporting bias for the permanent filters. Although no fractures have been reported to date for the other retrieval filters, the estimated number implanted is low. In addition, these filters are retrieved relatively soon after implantation. The mean (range) days before retrieval for Optease and Tulip are 16(3-48 days) and 11(2-20),[6,7] respectively, timeframes in which no Recovery filter fractures were reported.

Likelihood of Harm if the Problem Occurs: Filter fragments which remain attached to the IVC, or migrate to a similar location, are theoretically capable of causing tissue erosion and foreign body reactions of various kinds. However, as observed in these cases and from literature review, they are generally of little clinical consequence. Penetration of the IVC wall by intact filters in not infrequent (reported to occur from 0-41% of cases); however, serious injury is rare. Migration of metal fragments to the heart or lung presents the possibility of cardiac or pulmonary injury with serious clinical consequences. In patients with a patent foramen ovale, left sided embolism is possible, with attendant risk of stroke or other end organ damage. The likelihood of harm caused by fracture of the Recovery filter can be assessed as follows:

Likelihood of migration to heart or lung: 6(7)*/10,200, 0.06% (0.07%), or 1 in 1,700 (1457)
Likelihood of serious injury: 1/10,200, 0.01% or 1 in 10,200

* 6 fragments are known to have gone to heart or lung; the in vivo location of 1 fragment is unknown

Is the Product Essential to Health: Yes. It is particularly important in patients with a limited time frame of high risk of thromboembolism for whom anticoagulation if contraindicated or ineffective (about 20% or more of patients).

Is there an Alternative Available: Yes. Alternative IVC filters exist, but the ability to retrieve the Recovery filter in patients with transient risk of venous thromboembolism makes it an important treatment option for many patients.

Must the Problem Device be Removed or Corrected Surgically: Yes, in some cases.

Is the Problem Expected & Within an Acceptable Statistical Range: See answers above for Likelihood of Occurrence and Likelihood of harm. Statistical analysis of hazard rates for Recovery versus other filters is not directly possible, due to lack of comparable datasets. Filter fracture and consequent injury rates for Recovery are well below those reported in the literature, but substantially above those reported as MDRs by other filter manufacturers. For the reasons noted above, however – primarily retrievability features – data allowing a direct comparison of the recovery filter with any other IVC filter are not available.

Can the Problem be Corrected in the Field: Percutaneous retrieval of the filter fragments is sometimes possible, leading to correction/mitigation of the migration risk. However, when the fragment is in a difficult location, retrieval may be impossible or contraindicated.

Is the Problem or Health Hazard Obvious to the User: As mentioned above, filter fracture is a known complication of IVC filter placement, and information concerning this hazard has been placed in the Recovery IFU. However, there is no way to predict which patients will develop this complication. More fre-

quent monitoring of the filter once placed may facilitate discovery of abnormal placement (a *possible* but not proven predisposing factor for fracture) or indeed of a fractured filter, but could not prevent all potential adverse events.

Can the Product Continue to be Used with Proper Warnings: Yes.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

EXHIBIT 20

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 21

To Plaintiffs' Response to Bard's Motion for Protective Order

(Filed Under Seal)

EXHIBIT 22

To Plaintiffs' Response to Bard's Motion for Protective Order

From: Hudson, Brian [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=BHUDSON]
Date: 6/28/2011 3:27:38 PM
To: Bovee, Kevin [kevin.bovee@crbard.com], Modra, Chad [Chad.Modra@crbard.com]
Subject: RE: Fx - Talking Points
Attachments: Filter Data 6-27-11.doc

Kevin,

Here are answers that I have now.

· G2 Express was the new filter with snare tip loaded in the G2 delivery system. G2X was a new delivery system.

· There is a 510(k) number for Meridian, will need to get from Filter team

· Denali is under clinical study, will need to get from Filter team

· We do have the FDA presentation and associated meeting minutes available

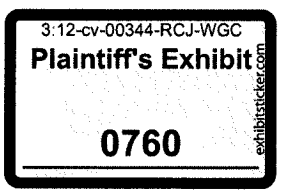
· We have charts available – most relevant attached.

Thanks,

Brian

From: Bovee, Kevin
Sent: Tuesday, June 28, 2011 5:41 AM
To: Hudson, Brian; Modra, Chad
Subject: RE: Fx - Talking Points

Thanks Brian.



· What is the difference between G2 Express (launched 8/08) and G2X (launched 1/09)?

· Is there a 510k reference # for Meridian?

· Denali (under clinical study) – what is the clinical study #?

Also,

· You mentioned a presentation which BPV conducted with FDA. Can I get a summary and/or results of the meeting / presentation?

· Are there existing trend charts, by product line? By rate, occurrence, or both?

Thanks,

Kevin

From: Hudson, Brian
Sent: Monday, June 27, 2011 8:27 PM
To: Bovee, Kevin; Modra, Chad
Subject: Fx - Talking Points

Kevin and Chad,

Here are the talking points for filter fracture.

Brian

Data from Launch through May 2011:

Product	# Fracture Complaints	Units Sold	Rate
SNF	8	80,187	0.010%
RNF	181	32,434	0.558%
G2	156	126,369	0.123%
G2X	42	41,841	0.100%
Eclipse	12	33,402	0.036%